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In the Supreme Court of the United States

BIOMEDICAL PATENT MANAGEMENT CORPORATION,
Petitioner,
v.
STATE OF CALIFORNIA,
DEPARTMENT OF HEALTH SERVICES,
Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

PETITION FOR A WRIT OF CERTIORARI

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QUESTIONS PRESENTED

1. Whether a state's waiver of Eleventh Amendment immunity in one action extends to a subsequent action involving the same parties and the same underlying transaction or occurrence.

2. Whether a state waives its Eleventh Amendment immunity in patent actions by regularly and voluntarily invoking federal jurisdiction to enforce its own patent rights.

RULE 29.6 STATEMENT

Biomedical Patent Management Company has no parent company, and no publicly held company owns more than 10% of its stock.

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PETITION FOR A WRIT OF CERTIORARI

Petitioner, Biomedical Patent Management Corporation ("BPMC"), respectfully petitions the Court for a writ of certiorari to review the judgment of the United States Court of Appeals for the Federal Circuit in this case.

OPINIONS BELOW

The opinion of the court of appeals (App., *infra*, 1a–28a) is reported at 505 F.3d 1328. The memorandum and order of the district court dismissing petitioner's complaint (App., *infra*, 29a–42a) is unreported but is available at 2006 WL 1530177. The order of the district court entering judgment (App., *infra*, 43a) is unreported.

JURISDICTION

The judgment of the court of appeals was entered on October 23, 2007. The jurisdiction of this Court rests on 28 U.S.C. § 1254(1).

CONSTITUTIONAL PROVISION INVOLVED

The Eleventh Amendment to the United States Constitution provides: "The judicial power of the United States shall not be construed to extend to any suit in law or equity, commenced or prosecuted against one of the United States by citizens of another state, or by citizens or subjects of any foreign state."

STATEMENT

States are major players in the patent market. Many of the largest universities and research institutions are state-owned, and their inventions increasingly contribute substantial revenues to the state fisc. In recent years, states have increasingly turned to the federal courts to maximize the value of their patent portfolios; through aggressive litigation, states have won judgments and settlement awards in the hundreds of millions of dollars.

While they embrace federal jurisdiction when it helps them to enhance their patent revenue streams, states simultaneously avoid federal jurisdiction when they themselves are faced with claims of patent infringement; in those circumstances, they assert sovereign immunity under the Eleventh Amendment. Although state officials acknowledge that this asymmetry is unfair—and although it distorts the market for inventions—they contend that the jurisprudence of sovereign immunity entitles them to the risk-free windfall of suing without being sued.

In companion cases decided nearly a decade ago, this Court determined that a state's mere participation in the federal patent system through commercial activities could not operate as a constructive waiver of the state's Eleventh Amendment immunity and that Congress had not permissibly abrogated state sovereign immunity as to the patent laws. See *Coll. Sav. Bank* v. *Fla. Prepaid Postsecondary Educ. Expense Bd.*, 527 U.S. 666 (1999); *Fla. Prepaid Postsecondary Educ. Expense Bd.* v. *Coll. Sav. Bank*, 527 U.S. 627 (1999). However, neither *College Savings Bank* nor *Florida Prepaid* upset the settled principle that a state waives its immunity through litigation conduct that demonstrates its willingness to resolve a dispute in federal court. Indeed, this Court has since reaffirmed that principle. See *Lapides* v. *Bd. of Regents of the Univ. Sys. of Ga.*, 535 U.S. 613 (2002).

This case concerns the scope of waiver by litigation conduct. Here, California voluntarily invoked federal jurisdiction to determine whether it was liable to BPMC for infringing a patent, thereby waiving its sovereign immunity. That case, however, was filed in an improper venue and was ultimately dismissed. When the case was refiled—to resolve precisely the same dispute as to the same patent between the same parties—California claimed immunity. The Federal Circuit embraced California's resuscitation of its once-waived immunity as to this dispute, in essence concluding that immunity is an artifact of a particular case, formally defined, that lives and dies with the docket number assigned by the clerk. The Eighth and Ninth Circuits have adopted a different approach; in their view, waiver attaches not to the case but to the transaction or occurrence at issue.

California's effort to invoke sovereign immunity selectively in this case is part of a larger scheme to use the federal courts as both a sword and a shield. California embraces federal patent jurisdiction when it seeks to benefit but avoids that jurisdiction when it faces liability. Through its frequent voluntary invocation of federal patent jurisdiction, however, California has unambiguously demonstrated that it is generally amenable to federal jurisdiction in these matters and has thereby waived its Eleventh Amendment immunity.

Because of the increased willingness of states to appeal to the federal courts for patent damages when it suits them, and the substantial impact that these lawsuits have on the market for inventions, BPMC respectfully requests this Court to resolve the uncertainty surrounding the scope of waiver by litigation conduct and to hold that California has waived its Eleventh Amendment immunity here.

A. Background

1. The State of California has an extensive and valuable patent portfolio. In 2006, for the twelfth consecutive year, the United States Patent and Trademark Office named the University of California "the leader among the nation's universities in developing new patents." UC Technology Transfer Annual Report 2006, at 3, http://www.ucop.edu/ott/genresources/documents/OTTRptFY06.pdf. As of June 30, 2006, the University of California system alone had contributed 3,316 active patents to the state's patent portfolio and had generated $210 million in annual revenue. *Id.* at 3, 14.

California has aggressively commoditized its patents by filing infringement actions in federal court. Since 1990, California has been the plaintiff voluntarily invoking federal jurisdiction in at least 21 patent suits, see App., *infra*, 99a–101a, and has won several judgments and settlements exceeding $100 million each.[1] Indeed, from 2000 to 2006 alone, California obtained over $900 million in judgments and settlements in patent-infringement actions. C.A. J.A. 53. The state's litigiousness is part of a conscious effort to increase licensing revenues; as Michael Ward, California's outside patent counsel, has explained, potential adversaries are "seeing that the University of California is aggressive and [willing] to take on people like Monsanto and get very favorable settlements * * *. The awareness is increasing." S. Qualters, *University Patent Work on Upswing*, NAT'L L.J., Nov. 19, 2007, at 8.

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[1] See P. Lattman, *Critics Take Aim At California's Patent Shield*, WALL ST. J., Nov. 13, 2007, at B1 ("As a plaintiff alleging patent infringement, the [University of California] has settled a claim against Genentech Inc. for $200 million, secured a payment of $185 million from Monsanto Co., and won a $30 million settlement from Microsoft Corp.").

While California zealously enforces its own patents in federal court, it resists answering charges that it has infringed others' patents, instead asserting sovereign immunity under the Eleventh Amendment. Since 1987, the state has invoked sovereign immunity to obtain dismissal of at least six federal patent actions.[2]

Although California is the leader in patent litigation, it is by no means alone. Since the implementation of the PACER system in the district courts in the 1990s, at least 32 states have filed at least 173 affirmative patent actions. See App., *infra*, 99a–117a. Meanwhile, invocations of state sovereign immunity in patent disputes have been frequent.[3]

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[2] Lattman, *supra* note 1; see, *e.g.*, *Genentech, Inc.* v. *Regents of the Univ. of Cal.*, 143 F.3d 1446 (Fed. Cir. 1998), *vacated*, 527 U.S. 1027 (1999); *New Star Lasers, Inc.* v. *Regents of the Univ. of Cal.*, 63 F. Supp. 2d 1240 (E.D. Cal. 1999); *Regents of the Univ. of Cal.* v. *Eli Lilly & Co.*, 119 F.3d 1559 (Fed. Cir. 1997); *Chew* v. *California*, 893 F.2d 331 (Fed. Cir. 1990).

[3] See, *e.g.*, *Fla. Prepaid Postsecondary Educ. Expense Bd.* v. *Coll. Sav. Bank*, 527 U.S. 627 (1999); *Baum Res. & Dev. Co.* v. *Univ. of Mass.*, 503 F.3d 1367 (Fed. Cir. 2007); *Vas-Cath Corp.* v. *Curators of the Univ. of Mo.*, 473 F.3d 1376 (Fed. Cir. 2007); *Tegic Commc'ns Corp.* v. *Bd. of Regents of Univ. of Tex. Sys.*, 458 F.3d 1335 (Fed. Cir. 2006); *Pennington Seed, Inc.* v. *Produce Exch. No. 299*, 457 F.3d 1334 (Fed. Cir. 2006) (Arkansas); *Xechem Int'l, Inc.* v. *Univ. of Tex. M.D. Anderson Cancer Ctr.*, 382 F.3d 1324 (Fed. Cir. 2004); *Regents of the Univ. of N.M.* v. *Knight*, 321 F.3d 1111 (Fed. Cir. 2003); *State Contracting & Eng'g Corp.* v. *Florida*, 258 F.3d 1329 (Fed. Cir. 2001); *Jacobs Wind Elec. Co., Inc.* v. *Fla. Dep't of Transp.*, 919 F.2d 726 (Fed.

2. This case concerns U.S. Patent No. 4,874,693 (filed Oct. 10, 1986) ("the '693 Patent"), which was issued for a groundbreaking advance in non-invasive prenatal screening for fetal abnormalities such as trisomy 21 (Down Syndrome). See App., *infra*, 77a–98a. Petitioner BPMC is the sole owner of the '693 Patent. BPMC licenses the patent to institutions and laboratories that perform prenatal screening, including the two dominant national reference laboratories—Quest Diagnostics and Laboratory Corporation of America—and the Mayo Clinic.

California's Department of Health Services ("DHS") manages the only sizable prenatal screening program in the nation that implements the procedure described in the '693 Patent without a license. Moreover, DHS has promulgated regulations preventing existing and potential licensees of the '693 Patent from practicing the invention in California except under license from DHS. See CAL. CODE REGS. tit. 17, §§ 6521–6527. Under the regulations, all fees for practicing the '693 invention in California must be remitted directly to the state. See *id.* § 6540.

The dispute between DHS and BPMC has resulted in three lawsuits.

B. Prior Proceedings

1. In August 1997, Kaiser Foundation Health Plan, Inc. ("Kaiser"), a subcontractor of DHS, filed an action against BPMC in the United States District Court for the Northern District of California, seeking

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Cir. 1990); *Competitive Techs., Inc.* v. *Fujitsu Ltd.*, 286 F. Supp. 2d 1118 (N.D. Cal. 2003) (Illinois).

No doubt, in the aftermath of *Florida Prepaid*, many additional patent holders with patent-infringement claims against states have opted simply not to file complaints.

a declaratory judgment of non-infringement or invalidity as to the '693 Patent ("the First Action"). DHS filed a complaint in intervention seeking the same relief, App., *infra*, 66a–69a, and was allowed to intervene over BPMC's objection.

BPMC filed a motion to dismiss for improper venue. After the motion was denied, BPMC answered DHS's complaint in intervention and asserted compulsory counterclaims, alleging four counts of patent infringement. *Id.* at 70a–76a. On reconsideration, the district court dismissed the case for improper venue. *Id.* at 54a–55a. The Federal Circuit dismissed Kaiser's appeal. *Id.* at 56a.

2. In May 1998, BPMC filed a complaint against DHS in a proper venue, the United States District Court for the Southern District of California ("the Second Action"). App., *infra*, 61a–65a. The complaint in the Second Action alleged the same four counts of patent infringement that had been alleged in BPMC's counterclaim in the First Action, and it sought the same relief. Compare *id.* at 63a–65a with *id.* at 74a–75a.

In its answer in the Second Action, DHS asserted an affirmative defense of Eleventh Amendment immunity. However, before that issue was resolved, the district court granted BPMC's motion for voluntary dismissal without prejudice, pursuant to Fed. R. Civ. P. 41(a)(2), so as to avoid duplicative litigation while *Florida Prepaid Postsecondary Education Expense Board* v. *College Savings Bank* was pending before this Court. App., *infra*, 44a–53a.

C. Proceedings Below

1. In February 2006, BPMC refiled its complaint against DHS in the United States District Court for

the Northern District of California, alleging the same four counts of patent infringement ("the Third Action"). App., *infra*, 57a–60a.[4] DHS moved to dismiss on the basis of Eleventh Amendment immunity. The district court granted DHS's motion. App., *infra*, 29a–42a.

The court found that the waiver of sovereign immunity in the First Action did not extend to the Third Action, because dismissal of the First Action was for improper venue. App., *infra*, 36a–37a. The court reasoned that, because dismissal for improper venue under Fed. R. Civ. P. 41(b) is without prejudice, it is equivalent to a voluntary dismissal under Rule 41(a)(1), which "leaves the situation as if the action never had been filed." *Id.* at 36a (citing 9 Wright & Miller, *Federal Practice and Procedure* § 2367, at 321 (2d ed. 1995)) (alteration and internal quotation marks omitted).

The court further found that California had not waived its immunity by exploiting federal courts' jurisdiction in patent-infringement actions. *Id.* at 40a–41a. After declaring that it was "troubled by the University of California's ability to reap the benefits of the patent system without being exposed to liability for infringement," the court characterized BPMC's argument as falling "under the rubric of constructive waiver" and thus deemed it foreclosed by this Court's decision in *College Savings Bank* v. *Florida Prepaid Postsecondary Education Expense Board*. *Id.* at 41a.

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[4] Even though they concerned the same parties and the same underlying transaction or occurrence, the First Action and the Third Action were governed by different venue requirements. See 28 U.S.C. §§ 1391, 1400(b); see also *Emerson Elec. Co.* v. *Black & Decker Mfg. Co.*, 606 F.2d 234, 238 (8th Cir. 1979) ("Venue in a declaratory judgment action for patent invalidity and noninfringement is governed by the general venue statute, not the patent infringement venue statute.") (citations and footnote omitted).

2. The Federal Circuit affirmed. App., *infra*, 1a–28a. The court acknowledged that "DHS's intervention in the [First Action] constituted a waiver of its sovereign immunity in that suit," App., *infra*, 8a; accord *Regents of the Univ. of N.M. v. Knight*, 321 F.3d 1111, 1124–1126 (Fed. Cir. 2003), but held that, "where a waiver of immunity occurs in an earlier action that is dismissed," the waiver "does not extend to the separate lawsuit," App., *infra*, 18a–19a. The court also rejected BPMC's contention that California's patent-litigation activities effected a waiver, agreeing with the district court that this was a "constructive waiver" theory foreclosed by *College Savings Bank*. *Id.* at 27a.

REASONS FOR GRANTING THE PETITION

When a state voluntarily invokes federal jurisdiction, it is settled that the state's Eleventh Amendment immunity is waived. However, the *scope* of the state's waiver is *not* settled. The courts of appeals have taken different approaches, and thus there is no uniform principle governing the scope of a state's waiver of Eleventh Amendment immunity.

This petition presents two related questions concerning the scope of such a waiver: *first*, whether a waiver is confined to the case in which it is initially made or instead extends to other cases involving the same parties and the same underlying transaction or occurrence; and *second*, whether a state's repeated invocation of federal jurisdiction to resolve issues of patent infringement effects a waiver that extends to suits in which the state is sued by a party seeking to resolve a patent dispute.

This Court should grant certiorari to settle the law on when a state's invocation of federal jurisdiction precludes it from asserting immunity in other cases.

I. THE COURT SHOULD GRANT CERTIORARI TO DECIDE WHETHER A STATE'S WAIVER OF ELEVENTH AMENDMENT IMMUNITY IN ONE ACTION EXTENDS TO A SUBSEQUENT ACTION INVOLVING THE SAME PARTIES AND THE SAME UNDERLYING TRANSACTION OR OCCURRENCE

The sovereign immunity of a state "is a personal privilege which it may waive at pleasure." *Clark* v. *Barnard*, 108 U.S. 436, 447 (1883). The privilege is waived "where a state voluntarily become[s] a party to a cause, and submits its rights for judicial determination." *Gunter* v. *Atl. Coast Line R.R. Co.*, 200 U.S. 273, 284 (1906). Once the privilege is waived, it is lost, as "the immunity of sovereignty from suit without its consent cannot be carried so far as to permit [a state] to reverse the action invoked by it and to come in and go out of court at its will, the other party having no right of resistance to either step." *Porto Rico* v. *Ramos*, 232 U.S. 627, 632 (1914).

This Court last addressed the waiver of sovereign immunity in *Lapides* v. *Board of Regents of the University System of Georgia*, 535 U.S. 613 (2002). In *Lapides*, the Court held that a state's voluntary removal of an action to federal court is "sufficient to waive the State's otherwise valid objection to litigation of a matter * * * in a federal forum." *Id.* at 624. The Court recognized that "[i]n large part the rule governing voluntary invocations of federal jurisdiction has rested upon the problems of inconsistency and unfairness that a contrary rule of law would create." *Id.* at 622.

As other courts have recognized, these "problems of inconsistency and unfairness" exist when a state waives its immunity in one case and then attempts to assert immunity in a case involving the same parties and the same underlying transaction or occurrence. By adopting a contrary position, the Federal Circuit abandoned the guidance of *Lapides* and added further confusion to whether a state must be deemed to have waived immunity in these circumstances. This Court should grant certiorari to settle the issue.

A. The Decision Below Is Incorrect

1. The position adopted by the Federal Circuit is fundamentally unfair and inconsistent with this Court's decision in *Lapides*. In *Lapides*, the Court confronted the question whether a state that invokes federal jurisdiction under 28 U.S.C. § 1441 is thereafter entitled to dismissal of the action under the Eleventh Amendment. In concluding that a state waives immunity by removing an action to federal court, this Court took a functional approach to waiver, emphasizing "that neither those who wrote the Eleventh Amendment nor the States themselves * * * would intend to create th[e] unfairness" that a contrary rule would allow. 535 U.S. at 622. A contrary rule, the Court explained, "would permit States to achieve unfair tactical advantages, if not in this case, in others." *Id.* at 621.

The reasoning of *Lapides* applies equally in the circumstances here. The same problems of "inconsistency and unfairness" that existed in *Lapides* exist when a state waives its Eleventh Amendment immunity and then seeks to assert immunity in a case involving the same parties and the same underlying transaction or occurrence. For example, under the Federal Circuit's reasoning, a state may intentionally invoke federal court jurisdiction *in the wrong forum*—where personal jurisdiction over the non-state party is lacking or venue is improper. Then, if the defendant succeeds in dismissing the action, the waiver becomes a nullity and the defendant is left unable to bring a new action to resolve the *identical* dispute in the *proper* forum. In short, the state may decide to litigate a matter in the court of its choosing or not at all.

A rule that entitles a state to impose a Hobson's choice on a private adversary is surely inconsistent with ordinary norms of equity and justice. As a result, "those who wrote the Eleventh Amendment," who did not "intend to create * * * unfairness," *Lapides*, 535 U.S. at 622, could not have foreseen that a state could legitimately condition its willingness to submit a dispute to the federal courts for resolution on a choice of venue forbidden by federal statute. A rule of immunity that allows a state to litigate on its own terms "undermines the integrity of the judicial system[,] wastes judicial resources, * * * and imposes substantial costs upon the litigants." *Hill* v. *Blind Indus. & Servs.*, 179 F.3d 754, 756 (9th Cir. 1999).

2. The Federal Circuit misapplied *Lapides* in holding that a waiver in one case has no bearing on a refiled action to resolve the same issue. The court reasoned that "even a waiver by litigation conduct must * * * be 'clear,'" and that "a waiver that does

not 'clearly' extend to a separate lawsuit generally would not preclude a State from asserting immunity in that separate action." App., *infra*, 20a; accord *id.* at 22a–23a. That very reasoning was rejected by this Court in *Lapides.* In response to the state's argument that it gave no "clear" indication that it intended to waive its immunity, the Court emphasized that, where "waivers effected by litigation conduct" are at issue, "[t]he relevant 'clarity'" must "focus on the litigation act the State takes that creates the waiver." 535 U.S. at 620. After all, the Court explained, "a State's actual preference or desire" might "favor selective use of 'immunity' to achieve litigation advantages." *Ibid.* In *Lapides*, the litigation act—removal—was clear, and the Court proceeded to determine the legal consequence of that act. See *id.* at 620–624. In this case, California's motion to intervene in the First Action over BPMC's objection was no less clear. The Federal Circuit's emphasis on a perceived lack of clarity was therefore misplaced.

The court of appeals also underestimated the potential for unfairness that results from allowing a state to litigate a dispute, if at all, in the venue of its choosing. The court opined that "venue considerations alone" are unlikely to govern a state's decision to assert immunity, App., *infra*, 22a, and that nothing in this particular case indicates that DHS had improper motives, *ibid.* That reasoning fails on both counts.

First, the importance of venue selection in litigation strategy should not be underestimated. As this Court said in *Stewart Organization, Inc.* v. *Ricoh Corp.*, 487 U.S. 22 (1988):

> Venue is often a vitally important matter, as is shown by the frequency with which parties

> contractually provide for and litigate the issue. Suit might well not be pursued, or might not be as successful, in a significantly less convenient forum. Transfer to such a less desirable forum is, therefore, of sufficient import that plaintiffs will base their decisions on the likelihood of that eventuality when they are choosing whether to sue in state or federal court.

Id. at 39–40. The issue is particularly charged in patent cases; as explained by the House Report on the Court of Appeals for the Federal Circuit Act of 1981:

> Patent litigation long has been identified as a problem area, characterized by undue forum-shopping and unsettling inconsistency in adjudications. * * * [T]he application of the law to the facts of a case often produces different outcomes in different courtrooms in substantially similar cases. As a result, some circuit courts are regarded as "pro-patent" and other "anti-patent," and much time and money is expended in "shopping" for a favorable venue.

H.R. REP. NO. 97-312, at 20–21 (1981) (footnote omitted); see also Patent Reform Act of 2007, H.R. 1908, 110th Cong. § 11 (as passed by House, Sept. 7, 2007); J. Creswell, *So Small a Town, So Many Patent Suits*, N.Y. TIMES, Sept. 24, 2006, § 3, at 1. Indeed, this Court has previously granted certiorari to address what constitutes proper venue in a patent case. See *Fourco Glass Co.* v. *Transmirra Prods. Corp.*, 353 U.S. 222, 229 (1957) (holding that "28 U.S.C. § 1400(b) is the sole and exclusive provision controlling venue in patent infringement actions"). Thus, the Federal Circuit was wrong in its belief that venue is of little consequence.

Second, immunity analysis does not focus on the state's motives in a particular case. As this Court recognized in *Lapides*, "[m]otives are difficult to evaluate, while jurisdictional rules should be clear." 535 U.S. at 621. Accordingly, the Court looked to the "unfair tactical advantages" that would arise "if not in this case, in others." *Ibid.* In light of the importance of venue and other waivable procedural guarantees, there surely is potential for a state to secure a litigation advantage through the selective, and inconsistent, assertion of Eleventh Amendment immunity.

B. The Decision Below Conflicts With Decisions Of Other Courts Of Appeals

In addition to being inconsistent with *Lapides*, the decision of the Federal Circuit conflicts with decisions of other courts of appeals regarding the scope of a voluntary waiver of Eleventh Amendment immunity.

1. Both the Eighth Circuit and the Ninth Circuit have adopted a functional approach to the scope of waiver and have held that a waiver in one action extends to an action involving the same parties and the same underlying transaction or occurrence. In *Rose* v. *U.S. Department of Education (In re Rose)*, 187 F.3d 926 (8th Cir. 1999), the Eighth Circuit assessed the scope of an Eleventh Amendment waiver by an arm of the State of Missouri, the Student Loan Program ("SLP"), which waived its immunity when it voluntarily submitted a proof of claim in a bankruptcy action. Cf. *Gardner* v. *New Jersey*, 329 U.S. 565, 574 (1947). When the debtor filed a discharge

action as to student loans for which SLP was the creditor, SLP claimed immunity in that "separate action." *Rose*, 187 F.3d at 929; see Fed. R. Bankr. P. 4007; see also *In re Rose*, 214 B.R. 372 (Bankr. W.D. Mo. 1997) (Bankr. No. 97-42803-2 and Adversary No. 97-4120-2). The Eighth Circuit rejected SLP's contention that the bankruptcy filing and the discharge proceeding were "separate cases for immunity purposes." *Rose*, 187 F.3d at 929. It held that the proceedings were "interrelated" and that "[d]isputes arising out of the adjudication of a single debt may be sufficiently intertwined so that a waiver in one aspect applies to the others as well." *Ibid.*

In *Schulman* v. *California (In re Lazar)*, 237 F.3d 967 (9th Cir. 2001), an arm of the State of California, the Board of Equalization ("BOE"), submitted proofs of claims for unpaid taxes in a Chapter 11 reorganization that was subsequently converted to Chapter 7. *Id.* at 971–972. After 20 reimbursement claims filed by the debtor were denied by another arm of the state, the Water Resources Control Board ("WRCB"), the bankruptcy trustee filed a Petition for Peremptory Writ of Administrative Mandamus against the WRCB in state superior court, seeking payment of the reimbursement claims. The trustee then removed the mandamus adversary action to the bankruptcy court pursuant to 28 U.S.C. § 1452(a), at which point the WRCB sought dismissal under the Eleventh Amendment. See 237 F.3d at 972–973. The Ninth Circuit held that immunity had been waived by the state in the bankruptcy proceeding and that the waiver extended to the mandamus adversary proceeding. In particular, the Ninth Circuit concluded that "the state waives its Eleventh Amendment immunity with regard to the bankruptcy estate's claims that arise from the same transaction or occurrence as the state's claim" and that "the Trustee's Mandamus Adversary arises out of the same transaction or occurrence as the BOE's proof of claim." *Id.* at 978–979. The Ninth Circuit reached that result notwithstanding the formal separation between the Chapter 11 and mandamus adversary actions. See *In re Lazar*, 200 B.R. 358 (Bankr. C.D. Cal. 1996) (Bankr. Nos. LA 92-39039, 92-39042 and Adversary No. LA 96-01575).[5]

The pragmatic approach reflected by *Rose* and *Lazar* stands in stark contrast to the formalistic approach adopted by the Federal Circuit in this case. If this case had arisen in the Eighth Circuit or the Ninth Circuit, the court of appeals would have evaluated whether the events underlying the First Action were sufficiently related to those underlying the Third Action—*i.e.*, part of the same "transaction or occurrence"—that the state's waiver in the First Action must be deemed to extend to the Third Action. The events underlying the First Action and the Third Action are not merely related; they are identical. The waiver in the First Action would therefore be found to extend to the Third Action under the functional test applied by the Eighth and Ninth Circuits. Indeed, this would be an even stronger case for a finding of waiver than *Rose* and *Lazar*, because the First Action and the Third Action are effectively the same, in that both sought to resolve the question whether the same acts by DHS infringed the '693 Patent.[6]

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[5] The Ninth Circuit has also rejected a state's attempt to gerrymander a waiver of Eleventh Amendment immunity in a slightly different context. In *Embury* v. *King*, 361 F.3d 562 (9th Cir. 2004), the court applied *Lapides* to "determine * * * the breadth of a state's waiver of Eleventh Amendment immunity when it removes a case from state to federal court." *Id.* at 562. The court held that, after waiving immunity through removal, a state cannot use immunity to prevent the plaintiff from amending the complaint to add related claims. *Id.* at 564–565. Rejecting the state's effort to "limit[]" its waiver, the court explained that the waiver applied "to claims asserted after removal as well as to those asserted before removal." *Id.* at 564; accord *Boone* v. *Pa. Office of Vocational Rehabilitation*, 373 F. Supp. 2d 484, 493 n.3 (M.D. Pa. 2005), *appeal dismissed*, No. 06-3240 (3d Cir. Jan. 16, 2007).

2. The First Circuit has also determined that a waiver of Eleventh Amendment immunity in one proceeding can extend to related proceedings. In *New Hampshire* v. *Ramsey*, 366 F.3d 1 (1st Cir. 2004), the New Hampshire Committee of Blind Vendors sued the State of New Hampshire for injunctive relief through its Department of Administrative Services. *Id.* at 9. On the state's motion, the initial complaint was dismissed for failure to exhaust administrative remedies. *Id.* at 10. Thereafter, the Blind Vendors

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[6] Both *Rose* and *Lazar* are bankruptcy cases. In light of this Court's subsequent decisions in *Tennessee Student Assistance Corp.* v. *Hood*, 541 U.S. 440 (2004), and *Central Virginia Community College* v. *Katz*, 546 U.S. 356 (2006), there is some question whether the issues in those cases might now be decided on the ground that states do not enjoy Eleventh Amendment immunity with respect to certain aspects of bankruptcy proceedings. However, *Rose* and *Lazar* applied general principles of Eleventh Amendment waiver, and even if there would now be a different ground for decision in those cases, there is no reason to question the precedential effect of the decisions on the general question of Eleventh Amendment immunity outside the bankruptcy context. See also *In re Omine*, 485 F.3d 1305, 1314–1315 (11th Cir. 2007) (affirming a bankruptcy court's exercise of jurisdiction over an arm of the State of Florida both because *Katz* precluded the claim to Eleventh Amendment immunity and because the state had in any event waived immunity as to matters that "arise[] out of the same transaction or occurrence" when it filed a proof a claim).

pursued administrative relief that ultimately led to review in federal court. *Id.* at 10–13. The First Circuit rejected the state's claim of Eleventh Amendment immunity in the subsequent litigation.

In the decision below, the Federal Circuit sought to distinguish *Ramsey* on the ground that "the critical act amounting to waiver of immunity" in that case was the state's "voluntary invocation of an administrative process that provided for federal judicial review." App., *infra*, 18a. But that was not the only basis for the First Circuit's finding of a waiver in *Ramsey*; the court also relied on the state's failure to raise an immunity claim in the earlier proceedings. 366 F.3d at 15–17. That circumstance—waiver of Eleventh Amendment immunity in the earlier proceeding—is obviously present here. So, too, is the other basis for a finding of a waiver in *Ramsey*: that the state in effect invoked federal jurisdiction in the later proceedings by moving to dismiss the earlier proceedings for lack of exhaustion, an event that was followed by the plaintiff's commencement of an administrative process that resulted in federal-court review. In this case, DHS can equally be said to have in effect invoked federal jurisdiction in the Third Action by filing the First Action in an improper venue, an event that was followed by BPMC's motion to dismiss the First Action and later commencement of the Third Action in a proper venue.

3. The decision of the Ninth Circuit in *City of South Pasadena* v. *Mineta*, 284 F.3d 1154 (9th Cir. 2002), on which the district court principally relied, see App., *infra*, at 35a–37a, and on which the court of appeals relied to some extent, see *id.* at 19a–20a, is not inconsistent with the position we advocate. In *Mineta*, the court refused to find that a waiver of

sovereign immunity in a 29-year-old case that had been voluntarily dismissed under Fed. R. Civ. P. 41(a)(1) extended to a later action between the parties. 284 F.3d at 1157–1158. Although the plaintiff sought a ruling on whether a waiver of Eleventh Amendment immunity may carry over to a subsequent action, the Ninth Circuit explicitly refused to reach the question because of its view that voluntary dismissal under Rule 41(a)(1) "leaves the situation as if the action never had been filed." *Id.* at 1157 (quoting 9 Wright & Miller, *Federal Practice and Procedure* § 2367, at 321 (2d ed. 1995)). The court held that "[Rule] 41(a)(1) provides a categorical rule that is much broader—one that disallows the 'carry-over' of *any* waivers from a voluntarily dismissed action to its reincarnation." *Id.* at 1158. The Ninth Circuit thus did not decide the scope of a waiver of Eleventh Amendment immunity in *City of South Pasadena.*[7]

II. THE COURT SHOULD GRANT CERTIORARI TO DECIDE WHETHER A STATE WAIVES ITS ELEVENTH AMENDMENT IMMUNITY IN PATENT ACTIONS BY REGULARLY AND VOLUNTARILY INVOKING FEDERAL JURISDICTION TO ENFORCE ITS OWN PATENT RIGHTS

By repeatedly invoking federal patent jurisdiction for its own benefit, California has demonstrated its willingness to resolve patent disputes in federal court and has waived its sovereign immunity to that extent. The Federal Circuit was wrong to conclude otherwise. A state has the right to own patents; it has the right to vindicate those rights in court; and it has the right to assert Eleventh Amendment immunity if it wishes to avoid being subject to the jurisdiction of a federal court. But a state has no right *simultaneously* to use the federal courts to extract revenue from industry competitors and to avoid any responsibility in those same courts for its own actions.

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[7] Even on its own terms, the Ninth Circuit's decision in *South Pasadena* has been rejected by at least one other court of appeals. In *Robinette* v. *Jones*, 476 F.3d 585 (8th Cir. 2007), the Eighth Circuit applied a rule of collateral estoppel to hold that a district court's immunity orders predating a voluntary dismissal were binding when the case was refiled.

The Eleventh Amendment is not a license to print money, and those who drafted it would never have embraced California's exploitative interpretation, which has little to do with sovereignty and everything to do with unjust financial enrichment. Whether California's conduct in litigating patent claims has effected a general waiver of its Eleventh Amendment immunity in that area is of paramount importance to inventors, who increasingly face market opposition from state-owned entities seeking to play by different rules. This Court should grant certiorari to decide the question.

A. The Decision Below Is Incorrect

All BPMC has ever sought is a level playing field for enforcing patent rights. When a state can enter and exit the judicial arena at its pleasure, non-state actors are severely handicapped. And when states manipulate the courts to gain a competitive edge in the patent market, they jeopardize the balance struck by Congress in creating incentives for inventors to innovate by giving them a time-limited monopoly.

1. California controls a massive machine for the development of patents and the exploitation of their economic potential. Among its well-known holdings are monopoly rights covering the vaccine for Hepatitis-B, cochlear implants, and the nicotine patch. UC Technology Transfer Annual Report 2006, *supra*, at 11. These, and the vast majority of California's other patent activities, are initiated within the University of California system—which, as an arm of the state, enjoys Eleventh Amendment immunity.[8] The University's Technology Transfer Office purposely cultivates a reputation for litigiousness so as to maximize the returns it reaps in the marketplace. See *supra* pp. 4–5. It is very successful. Whereas experts estimate that less than 5% of all patents are ever licensed commercially, see M. Lemley, *Rational Ignorance at the Patent Office*, 95 NW. U. L. REV. 1495, 1507 & n.53 (2001), California had 1811 licenses on its 3316 active patents. UC Technology Transfer Annual Report 2006, *supra*, at 14.

A key component of the success of California's licensing operation is its highly publicized propensity for filing patent actions in federal court. Since 1990, the state or one of its arms has filed at least 20 such actions, including 15 patent-infringement suits. See App., *infra*, 99a–101a. These cases bring in considerable revenue for the state and lend credibility to its actual and implied threats of litigation during licensing negotiations.

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[8] California has a single source of Eleventh Amendment immunity that is shared by all arms of the state. See *In re Charter Oak Assocs.*, 361 F.3d 760, 772 (2d Cir. 2004); *Lazar*, 237 F.3d at 979 n.13; *Wyo. Dep't of Transp.* v. *Straight (In re Straight)*, 143 F.3d 1387, 1391 (10th Cir. 1998).

In short, the federal courts are a vital component of California's efforts to extract revenue from its patent portfolio. However, when the tables are turned and the court system becomes an inconvenient obstacle, California simply invokes immunity and walks away. See *supra* note 2.

The contrast between California's behavior as an inventor and its behavior as a user of inventions demonstrates the manifest unfairness of its conduct. In this case, California seeks to free-ride on a widely adopted invention at the expense of the inventor, who has been prevented from seeking judicial relief against California for its own infringement—or even from licensing the invention to private parties in the state. See CAL. CODE REGS. tit. 17, §§ 6521–6527. However, the state is taking a notably different tack in *Regents of the University of California* v. *DakoCytomation California, Inc.*, No. 2006-1334 (Fed. Cir. filed Mar. 30, 2006). In that case, which is before the same federal district court—indeed the same federal district judge—where California now claims immunity, the state seeks to enjoin the manufacture and sale of a breast-cancer detection kit that allegedly infringe its own patent.

2. California's bipolar response to patent lawsuits runs counter to this Court's mandate in *Lapides* that the benefits of sovereign immunity are not to be used to pursue unfair and inconsistent results. *Lapides* spoke to how this Court's waiver jurisprudence has rested on these considerations, and how "those who wrote the Eleventh Amendment" would never have intended to create this type of unfairness. 535 U.S. at 622. If it is not unfair for the most successful exploiter of federal patent jurisdic-

tion to avoid defending itself under the same rules, then that principle is without meaning.

This Court has long understood the dangers of allowing a sovereign "to come in and go out of court at its will." *Ramos*, 232 U.S. at 632. This case presents an extreme example of that predicament. The federal courts are not under the control of the states and do not exist to enhance their bankrolls. They exist to adjudicate cases. And when they are handcuffed by unequal authority in identical cases, the results can be nothing but unfair.

The unfairness is not hidden. The district court declared itself "troubled" by this phenomenon. App., *infra*, 40a. The state's deputy attorney general agrees: "It's not fair but it's the current state of the law." Lattman, *supra* note 1. Moreover, members of this Court have acknowledged the potential for unfairness when firms "use patents not as a basis for producing and selling goods but, instead, primarily for obtaining licensing fees." *eBay* v. *MercExchange, L.L.C.*, 126 S. Ct. 1837, 1842 (2006) (Kennedy, J., joined by Stevens, Souter, and Breyer, JJ., concurring). That danger is even more pronounced when the firm is a player as large as California and seeks to use patents as a one-way income stream.

3. Through its pervasive use of the federal courts to resolve patent disputes, California has waived its immunity by litigation conduct. The Federal Circuit misunderstood BPMC's position, conflating waiver by litigation conduct with "constructive waiver." App., *infra*, 27a. The latter doctrine was rejected in *College Savings Bank*, where this Court determined that a state does not waive its Eleventh Amendment immunity by voluntarily participating in a federal program. 527 U.S. at 676–687. As this Court subse-

quently observed in *Lapides*, however, "*College Savings Bank* distinguished the kind of constructive waivers repudiated there from waivers effected by litigation conduct." 535 U.S. at 620; see, *e.g.*, *Coll. Sav. Bank*, 527 U.S. at 676 ("Nor is this a case in which the State has affirmatively invoked our jurisdiction.").

Thus, although, under *College Savings Bank*, California's mere participation in the patent marketplace does not effect a waiver of sovereign immunity, California's massive exploitation of the U.S. patent system is not merely commercial activity. Its continuous use of the federal courts themselves demands a different inquiry when evaluating California's amenability to suit in those same courts.

4. This Court has a sizable jurisprudence on how to determine whether a party has expressed a willingness to submit to a court's jurisdiction. As Justice Kennedy observed in *Wisconsin Department of Corrections* v. *Schacht*, 524 U.S. 381 (1998), "[Eleventh Amendment] immunity bears substantial similarity to personal jurisdiction requirements." *Id.* at 394 (concurring opinion). A version of the "minimum contacts" standard of *International Shoe Co.* v. *Washington*, 326 U.S. 310 (1945), is readily applicable to the Eleventh Amendment issue here. Just as a corporation with sufficient contacts with a jurisdiction may reasonably be required "to defend the particular suit which is brought there," *id.* at 317, a state that engages in sufficient voluntary conduct in federal courts may reasonably be required to defend similar suits brought there. Under whatever standard is adopted, however, California has waived its Eleventh Amendment immunity, given the frequency with which it has availed itself of federal patent jurisdic-

tion in recent years. Cf. *Met Life* v. *Robertson-Ceco*, 84 F.3d 560, 569 (2d Cir. 1996) (for purposes of general jurisdiction, "contacts are commonly assessed over a period of years prior to the plaintiff's filing of the complaint").

B. The Question Presented Is An Important One And This Case Is The Right Vehicle For Deciding It

Whether a state's pervasive invocation of federal patent jurisdiction operates to waive its sovereign immunity is a question of fundamental importance. California's ubiquity in the patent marketplace redirects hundreds of millions of dollars in areas that are critical to the nation's competitiveness in emerging technologies and healthcare. Although California is the leader of the states in this regard, it is by no means alone in adopting an indefensibly asymmetric approach to federal patent jurisdiction. Compare App., *infra*, 99a, 101a–117a with *supra* notes 2–3. As Judge Newman acknowledged in the aftermath of *College Savings Bank* and *Florida Prepaid*, "there is an increasing urgency, as the states enter the private competitive arena governed by the laws of intellectual property, to establish fair relationships and just recourse." *Xechem*, 382 F.3d at 1335 (separate opinion).

Although there is no circuit conflict on this question, that is not a basis for awaiting another case. Because the Federal Circuit exercises exclusive jurisdiction over patent appeals, see 28 U.S.C. §§ 1295(a)(1), 1338, no such conflict can or will emerge.

Indeed, it is not clear that another case presenting this question will arise even in the Federal Circuit. Litigants in patent disputes are rational market actors. As a result, it is unlikely that another patent-holder will pursue this same issue through the district court and the Federal Circuit, where the decision in this case is binding precedent, simply for the opportunity to file a petition for a writ of certiorari. This case may therefore be the *only* vehicle for resolving the issue.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted.

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JANUARY 2008

APPENDIX

APPENDIX A

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

No. 2006-1515

BIOMEDICAL PATENT MANAGEMENT CORPORATION

Plaintiff-Appellant,

v.

STATE OF CALIFORNIA, DEPARTMENT OF HEALTH SERVICES

Defendant-Appellee

Andrew J. Dhuey, of Berkeley, California, argued for plaintiff-appellant. With him on the brief was *Richard Kirk Cannon.*

Susan J. King, Deputy Attorney General, United States Department of Justice, of San Francisco, California, argued for defendant-appellee.

Appealed from: United States District Court for the Northern District of California

Judge Marilyn Hall Patel

DECIDED: October 23, 2007

Before RADER and GAJARSA, *Circuit Judges*, and O'MALLEY, *District Judge*.

O'MALLEY, *District Judge.*[*]

The issue presented in this appeal is whether a State is entitled to assert its sovereign immunity under the Eleventh Amendment where the State intervened in an earlier, related action that was dismissed for improper venue. The district court concluded that a State was entitled to assert its Eleventh Amendment sovereign immunity in those circumstances and, accordingly, granted a motion to dismiss on that ground filed by Defendant-Appellee State of California, Department of Health Services ("DHS"). Plaintiff-Appellant, Biomedical Patent Management Corporation ("BPMC"), appeals that decision. Because we agree that DHS's initial waiver of Eleventh Amendment sovereign immunity does not extend to this case or judicially estop DHS from asserting immunity in this case, we affirm.

I

BPMC alleges that it is the owner of United States Patent No. 4,874,693 ("the '693 patent"), entitled "Method for Assessing Placental Dysfunction," and issued on October 17, 1989. The '693 patent describes a method for screening birth defects in pregnant women, though a detailed description of the patent is not necessary to resolve the issues presented in this appeal. BPMC alleges in this case that DHS performs laboratory services, and induces others to perform services, that infringe the '693 patent. It asserts four claims against DHS: claims for literal patent infringement, both directly and by inducement; and claims for patent infringement under the doctrine of equivalents, both directly and by inducement. For relief, BPMC seeks money damages, treble damages for willful infringement, prejudgment interest, costs, expenses, and attorneys fees. As indicated below, this litigation is not the first litigation between these parties involving the '693 patent.

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[*] Honorable Kathleen M. O'Malley, District Judge, United States District Court for the Northern District of Ohio, sitting by designation.

A. The 1997 Lawsuit

On August 28, 1997, Kaiser Foundation Health Plan, Inc. ("Kaiser"), a subcontractor of DHS, filed a declaratory judgment action against BPMC in the United States District Court for the Northern District of California, seeking a declaratory judgment that the DHS screening program does not infringe the '693 patent and that the '693 patent is invalid (hereinafter, "the 1997 lawsuit").[1] DHS moved to intervene in the 1997 lawsuit, attaching a complaint in intervention that also sought a declaration of non-infringement and invalidity as to the '693 patent. The district court granted DHS's motion to intervene over BPMC's objection. At that time, BPMC asserted a compulsory counterclaim against DHS for infringement of the '693 patent, including a prayer for money damages. The compulsory counterclaim in that lawsuit contained the same four counts BPMC asserted in its Complaint in the instant action. Thereafter, BPMC filed a motion to dismiss the action for improper venue pursuant to Fed. R. Civ. P. 12(b)(3), which the district court granted. The 1997 lawsuit was dismissed in its entirety, without prejudice, on May 6, 1998.

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[1] Although not part of the allegations contained in BPMC's Complaint in the present case, the district court took judicial notice of several court filings from prior litigation between these parties. We also consider these court filings, which are matters of public record, for purposes of this appeal. Neither party argues that the district court improperly took notice of these filings, and we do not find that the district court abused its discretion in doing so. *See Lee v. City of Los Angeles*, 250 F.3d 668, 689 (9th Cir. 2001) ("We review a district court's decision to take judicial notice for abuse of discretion.").

B. The 1998 Lawsuit

On May 11, 1998, five days after dismissal of the 1997 lawsuit, BPMC filed a new action against DHS for infringement of the '693 patent in the United States District Court for the Southern District of California (hereinafter, "the 1998 lawsuit").[2] DHS answered and asserted the defense of sovereign immunity,[3] but did not assert a counterclaim.

Shortly after the 1998 lawsuit was filed, the Supreme Court granted a petition for a writ of certiorari to review this court's decision in *Coll. Sav. Bank*

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[2] BPMC also filed a separate lawsuit against Kaiser in the United States District Court for the Southern District of California, a case that, upon motion by DHS, was consolidated with BPMC's suit against DHS. Kaiser filed a counterclaim for declaratory judgment of non-infringement and invalidity as to the '693 patent in that action. Ultimately, Kaiser was dismissed from the consolidated action after BPMC entered into a covenant not to sue Kaiser and voluntarily dismissed its claims against Kaiser.

[3] All references to "sovereign immunity" in this opinion are to Eleventh Amendment sovereign immunity. DHS attempts to distinguish between a State's sovereign immunity under the Eleventh Amendment and its so-called inherent sovereign immunity, arguing that a State may waive one but not the other in federal court. We express no opinion as to this argument, as it is unnecessary to reach it to resolve the issues presented in this appeal.

v. Florida Prepaid Postsecondary Educ. Expense Bd., 148 F.3d 1343, 1355 (Fed. Cir. 1998), *cert. granted*, 525 U.S. 1064 (Jan. 8, 1999) (No. 98-531), in which we held that Congress, through the Patent and Plant Variety Protection Remedy Clarification Act ("Patent Remedy Act"), validly abrogated the sovereign immunity of the States to suit for patent infringement. Because of the potential impact of the Supreme Court's pending decision in *Florida Prepaid* on the 1998 lawsuit, BPMC sought to voluntarily dismiss the 1998 lawsuit without prejudice under Fed. R. Civ. P. 41(a)(2) to await that decision. Although DHS opposed the voluntary dismissal to the extent that it was without prejudice, the district court dismissed the case without prejudice on November 17, 1998.

On June 23, 1999, the Supreme Court issued its decision in *Florida Prepaid*, reversing the decision of this court and concluding that Congress' abrogation of State sovereign immunity from patent infringement claims was invalid. *Fla. Prepaid Postsecondary Educ. Expense Bd. v. Coll. Sav. Bank*, 527 U.S. 627, 630 (1999). As a result of Florida Prepaid, States retained their sovereign immunity to suit for patent infringement.

C. The Present Lawsuit

On February 2, 2006, BMPC [*sic*] filed the present lawsuit against DHS in the United States District Court for the Northern District of California, the same venue in which BMPC [*sic*] had successfully moved to dismiss the 1997 lawsuit for improper venue.[4] DHS moved to dismiss this case on the ground that sovereign immunity under the Eleventh Amendment barred BPMC's claims. The district court granted the motion and dismissed the case. *Biomedical Patent Mgmt. Corp. v. Cal., Dept. of Health Servs.*, No. 06-00737, 2006 WL 1530177, at *7 (N.D. Cal. June 5, 2006). BMPC [*sic*] filed a timely notice of appeal.

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[4] As to why it filed an action in a venue that it previously fought as improper, BMPC explains only that "[c]ircumstances no longer dictated that suit be resumed in San Diego."

II

BPMC does not dispute that DHS, as an arm of the State of California, generally is accorded Eleventh Amendment immunity. *See, e.g., Alden v. Maine*, 527 U.S. 706, 756 (1999) (observing that an arm of a State may assert sovereign immunity). It has long been recognized, however, that a State's sovereign immunity is "a personal privilege which it may waiver at its pleasure." *Coll. Sav. Bank v. Fla. Prepaid Postsecondary Educ. Expense Bd.*, 527 U.S. 666, 675 (1999) (quoting *Clark v. Barnard*, 108 U.S. 436, 447 (1883)); *see also Tegic Commc'ns Corp. v. Bd. of Regents of the Univ. of Tex. Sys.*, 458 F.3d 1335, 1340 (Fed. Cir. 2006) (explaining that the Eleventh Amendment "enacts a waivable immunity from suit, not a 'non-waivable limit on the federal judiciary's subject-matter jurisdiction.'" (quoting *Idaho v. Coeur d'Alene Tribe*, 521 U.S. 261, 267 (1997))). As the Supreme Court has explained, "[w]hile this immunity from suit is not absolute, we have recognized only two circumstances in which an individual may sue a state." *Coll. Sav. Bank*, 527 U.S. at 670. Those circumstances occur where Congress validly authorizes such a suit "in the exercise of its power to enforce the Fourteenth Amendment," or where a State has waived its sovereign immunity by consenting to suit. *Id.* In the present case, only the latter circumstance is at issue. "Generally, we will find a waiver either if the State voluntarily invokes our jurisdiction, or else if the State makes a clear declaration that it intends to submit itself to our jurisdiction." *Id.* at 676-77 (internal quotation and citations omitted).

As an initial matter, it is clear that, by intervening and asserting claims against BPMC in the 1997 lawsuit, DHS voluntarily invoked the district court's jurisdiction and, thus, waived its sovereign immunity for purposes of that lawsuit. "[I]t has long been established that a state waives its Eleventh Amendment immunity when it consents to federal court jurisdiction by voluntarily appearing in federal court." *Regents of the Univ. of N.M. v. Knight*, 321 F.3d 1111, 1124 (Fed. Cir. 2003) (citing *Clark v. Barnard*, 108 U.S. 436, 447 (1883)); *see also Gunter v. Atl. Coast Line R.R. Co.*, 200 U.S. 273, 284 (1906) ("[W]here a state voluntarily become[s] a party to a cause, and submits it rights for judicial determination, it will be bound thereby, and cannot escape the result of its own voluntary act by invoking the prohibitions of the 11th Amendment."). Indeed, as it relates specifically to intervention, the Supreme Court held over 100 years ago in *Clark* that "the voluntary appearance of [a] state in intervening as a claimant [in an interpleader action]" constitutes a waiver of Eleventh Amendment immunity. *Clark*, 108 U.S. at 447-48. The Supreme Court recently reaffirmed this proposition. *See Lapides v. Bd. of Regents of the Univ. Sys. of Georgia*, 535 U.S. 613, 619 (2002) (citing *Clark* with a parenthetical explanation that a "State's 'voluntary appearance' in federal court as an intervenor avoids Eleventh Amendment inquiry."). In addition, DHS's intervention also waived immunity as to all compulsory counterclaims that BPMC asserted in that lawsuit. *See Knight*, 321 F.3d at

1125-26. Based on well-established Eleventh Amendment jurisprudence, therefore, DHS waived its sovereign immunity in the 1997 lawsuit, at least for purposes of that lawsuit.[5]

Having found that DHS's intervention in the 1997 lawsuit constituted a waiver of its sovereign immunity in that suit, the question we must resolve in this case is when, if ever, a waiver of immunity in an earlier lawsuit prevents a State from asserting sovereign immunity in a later lawsuit between the same parties. BPMC asserts two grounds upon which it premises its contention that DHS's earlier waiver should prevent it from asserting sovereign immunity in this case: (1) DHS's waiver in the 1997 lawsuit extends or carries over to the instant lawsuit because the instant lawsuit involves the same subject matter and same parties; and (2) DHS should be judicially estopped from asserting immunity because the district court in the 1997 lawsuit accepted DHS's jurisdictional arguments in allowing DHS to intervene. In addition, BPMC advances two other arguments, unrelated to the waiver in the 1997 lawsuit, as to why DHS is not entitled to sovereign immunity in this case: (1) the conduct of the State of California in the patent system, and particularly patent litigation, operates as a general waiver for all California State defendants participating in patent suits; and (2) a recent Supreme Court decision, *Central Virginia Community Coll. v. Katz*, 546 U.S. 356 (2006), implicitly overruled *Florida Prepaid* such that sovereign immunity is no longer available in patent infringement actions. We address these arguments in turn.

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[5] DHS's argument to the contrary is unavailing. DHS argues that, at the time it intervened in 1997, it was not well-established that a state's intervention in a lawsuit amounted to a waiver of sovereign immunity. As demonstrated by the long-standing case law cited in this opinion, that argument is without support. We note, moreover, that DHS's reliance on *State Contracting & Eng'g Corporation v. Florida*, 258 F.3d 1329 (Fed. Cir. 2001) is misplaced. Quite simply, the filing of a protective counterclaim, as the State did in that case, is qualitatively different from the affirmative act of intervening in a lawsuit in which one has not otherwise been made a party, as DHS did in 1997.

A

BPMC first argues that DHS's waiver in the 1997 lawsuit extends or carries over to the instant lawsuit because this action involves the same subject matter and the same parties. This court applies Federal Circuit law, rather than regional circuit law, to the issue of Eleventh Amendment waiver. *Knight*, 321 F.3d at 1123-24. We review de novo a district court's judgment of dismissal on Eleventh Amendment grounds. *Id.* at 1124; *see also Tegic*, 458 F.3d at 1339 ("The constitutional issue of Eleventh Amendment immunity is given plenary review.").

In rejecting BPMC's first theory, the district court primarily relied on a Ninth Circuit case, *City of S. Pasadena v. Mineta*, 284 F.3d 1154 (9th Cir. 2002), though recognizing that Federal Circuit law should be applied, to the extent that it exists. *Biomedical Patent Mgmt. Corp.*, 2006 WL 1530177, at *3-4. In *City of S. Pasadena*, the Ninth Circuit held that the State of California's waiver of immunity in an earlier lawsuit, one that was voluntary dismissed under Fed. R. Civ. P. 41(a)(1), did not carry over to a re-filed action involving the same dispute. *City of S. Pasadena*, 284 F.3d at 1157-58. The court found that the voluntary dismissal under Rule 41(a)(1) left "the situation as if the action never had been filed," *id.* at 1157 (citing 9 Charles Alan Wright & Arthur R.

Miller, Federal Practice and Procedure § 2367 (2d ed.1995)), explaining that the result of such a dismissal is that "any future lawsuit based on the same claims is an entirely new lawsuit unrelated to the earlier (dismissed) action." *Id.* The Ninth Circuit held that, because a case filed after a Rule 41(a)(1) dismissal is an entirely new action, no waivers from a voluntarily dismissed action are carried-over to such a re-filed suit, including a State's Eleventh Amendment waiver. *Id.*

The district court in this case found that, like a dismissal under Rule 41(a)(1), a dismissal for improper venue "leaves the situation as if the action had never been filed." *Biomedical Patent Mgmt. Corp.*, 2006 WL 1530177, at *4 (citing 9 Charles Alan Wright & Arthur R. Miller, Federal Practice and Procedure § 2373 n.8 (2d ed.1995)). Accordingly, the district court held that the dismissal of the 1997 lawsuit disallowed the carry-over of DHS's waiver of immunity to any later action, and, therefore, that DHS was entitled to raise sovereign immunity in this case. *Id.*

On appeal, BPMC argues that the district court erred because it should have applied the rule set forth in *Lapides*, which was decided after *City of S. Pasadena*. In *Lapides*, the Supreme Court held that a State's removal of a case to federal court constituted voluntary invocation of the court's jurisdiction and, accordingly, waiver of the State's Eleventh Amendment sovereign immunity. *Lapides*, 535 U.S. at 624. In that case, an arm of the State of Georgia, sued as a defendant, removed a case to federal district court and then argued that it was immune from suit in federal court by virtue of the Eleventh Amendment. *Id.* at 616. The Supreme Court rejected that argument, explaining that "[i]t would seem anomalous or inconsistent for a State both (1) to invoke federal jurisdiction, thereby contending that the 'Judicial power of the United States' extends to the case at hand, and (2) to claim Eleventh Amendment immunity, thereby denying that the 'Judicial power of the United States' extends to the case at hand." *Id.* at 619. In doing so, the Court first noted well-established precedent holding that a State's voluntary appearance in federal court constituted a waiver of Eleventh Amendment sovereign immunity. *Id.* (citing *Gardner v. New Jersey*, 329 U.S. 565, 574 (1947); *Gunter*, 200 U.S. at 284; *Clark*, 108 U.S. at 447). The Court then held that, because removal is a form of voluntary invocation of a federal court's jurisdiction, removal is "sufficient to waive the State's otherwise valid objection to litigation of a matter (here of state law) in a federal forum." *Id.* at 624. In addition, the Supreme Court distinguished between the constructive waivers repudiated in *Col. Sav. Bank*, *see infra* Part II.C, and waivers effected by affirmative litigation conduct, noting that waiver by litigation conduct "rests upon the [Eleventh] Amendment's need to avoid inconsistency, anomaly, and unfairness, and not upon a State's actual preference or desire, which might, after all, favor selective use of 'immunity' to achieve litigation advantages." *Id.* at 620.

BPMC focuses on two aspects of *Lapides* to argue that DHS's 1997 waiver of immunity extends to the present case. First, BPMC places great significance on the Supreme Court's use of the word "matter" in holding that voluntary invocation of a federal court's jurisdiction waives a State's "otherwise valid objection to litigation of the matter in a federal forum." *Id.* at 624 (emphasis added). BPMC argues that "matter" signifies the subject matter of the lawsuit, not the case at hand, such that the waiver would apply to a later lawsuit involving the same subject matter. Second, BPMC focuses on the distinction drawn by the Supreme Court between a constructive waiver and a waiver by litigation conduct, arguing that the principles behind the rule governing waiver by affirmative litigation conduct -- avoiding unfairness and inconsistency -- should apply here to prevent DHS from asserting sovereign immunity in this case.

Neither of BPMC's arguments compels the result it urges. First, there is no reason to place significance on the Supreme Court's use of the term "matter" in *Lapides*, and BPMC offers none other than its own self-serving interpretation. Even if the term "matter" can be read, as BPMC suggests, to mean "subject matter" rather than "case" (or "action," "litigation," "lawsuit," etc.), BPMC's contention is belied by the Court's other statements in *Lapides*. Elsewhere in the opinion, the Court states that it would be inconsistent to allow a State to invoke jurisdiction for the "case at hand" and then to claim Eleventh Amendment immunity, thereby denying that jurisdiction extends to the "case at hand." *Id.* at 619 (emphasis added). The Court also explains that it would be unfair to allow a State to take both positions in "the same case." *Id.* (emphasis added). Certainly "the case at hand" and "the same case" indicate more narrow parameters for the scope of the waiver, and the semantic game in which BPMC attempts to engage actually cuts against its position.

In addition, we also reject BPMC's argument that the need to prevent unfairness and inconsistency requires a finding that DHS cannot assert immunity in the present lawsuit. BPMC misses one critical point that runs through almost all of the case law on which it relies: the waivers found in the cases cited by BPMC were based on actions by a State in the same case, not in cases that are either separated by a dismissal or cases that are entirely different actions. *Lapides* itself, of course, did not involve the effect of waiver of immunity in one case on a State's ability to later assert immunity in a separate case; it involved waiver based on actions that occurred in the same action. This is a common thread in the authority on which BPMC relies.

In *Gunter*, for example, the Supreme Court held only that a State's waiver extended to an ancillary proceeding in the same matter, not to a separate or independent action. 200 U.S. at 292. In that case, a railroad company sought to enforce an injunction against the State of South Carolina that prohibited the State from collecting taxes from the railroad. *Id.* at 281. The injunction arose from an action twenty-five years earlier, when a shareholder of the railroad company brought an action to enjoin the collection of taxes from the railroad, claiming that an exemption granted by the South Carolina legislature prevented such collection. *Id.* at 278. The State did not raise the defense of sovereign immunity in the shareholder's action for an injunction, and the result was a decree enjoining the State from collecting the taxes, which was affirmed by the Supreme Court. *See Humphrey v. Pegues*, 83 U.S. 244 (1872). Twenty-five years later, the State sought to collect back taxes from the railroad's successor for the previous twenty years, and the railroad's successor brought the case to federal court to enforce the injunction. *Gunter*, 200 U.S. at 281. At that time, the State asserted Eleventh Amendment sovereign immunity, but the Supreme Court held that an immunity defense was not available to the State at that stage. *Id.* at 284, 292. Ultimately, the Court found that the State was enjoined from collecting the taxes at issue. Id.

BPMC argues that *Gunter* supports its position because that case involved two separate actions, according to BPMC, in which waiver of immunity in an earlier action was held to carry over to a later action. A closer reading of *Gunter*, however, reveals that the disputes between the railroad and the State were part of one continuous action, a point that was critical to the Supreme Court's determination that the State could not assert immunity in the "later" action. In *Gunter*, when the railroad sought to enforce the injunction twenty-five years later, it did not file a new case; rather, "[t]he petition which initiated the proceeding was filed as ancillary to the original *Pegues Case*, and was entitle[d] and numbered as of that cause. It referred to the prior proceedings in the cause, including the perpetual injunction therein issued . . ." *Id.* at 281 (emphasis added). That fact was crucial. As the Supreme Court explained, "[i]ndeed, the proposition that the 11th Amendment . . . control[s] a court of the United States in administering relief, although the court was acting in a manner ancillary to a decree rendered in a cause over which it had jurisdiction, is not open for discussion." *Id.* at 292 (emphasis added). As such, *Gunter* does not support BPMC's position that a waiver of sovereign immunity extends to a separate lawsuit; it involved a waiver in one continuous action, though one that continued for an extended period of time.

Likewise, in *Vas-Cath Corp. v. Curators of the Univ. of Missouri*, 473 F.3d 1376 (Fed. Cir. 2007), which BPMC submitted as supplemental authority on appeal, this court found that the waiver of Eleventh Amendment sovereign immunity extended to a later phase of a continuous proceeding. In that case, the University of Missouri initiated interference proceedings at the Patent and Trademark Office ("PTO"), then, after receiving a favorable ruling from the PTO, asserted sovereign immunity when the losing party sought review of the PTO's determination in federal court. *Vas-Cath*, 473 F.3d at 1378. This court held that the University, having voluntarily invoked and participated in PTO proceedings, was not entitled to assert sovereign immunity to bar adjudication of the appeal in federal court. *Id.* at 1383-84. In reaching that conclusion, we found that proceedings in the PTO bear "strong similarities" to civil litigation and, based on *Lapides*, Missouri's voluntary invocation of and participation in PTO proceedings constituted a waiver of immunity in those proceedings. *Id.* at 1382-83. Significantly, we noted that "the interference proceeding is a multi-part action with appeal as of right, starting in the PTO and culminating in court." *Id.* at 1382. Further, "[t]he civil action authorized by [35 U.S.C.] § 146 is not a new claim, but an authorized phase of the interference proceeding that is conducted by the PTO and is subject to judicial review." *Id.* (emphasis added). As with *Gunter*, the holding in *Vas-Cath* does not support BPMC's argument that a waiver of immunity applies to a separate proceeding; that case involved a waiver in a later phase of one continuous action. *Vas-Cath*, therefore, also does not support the result that BPMC urges in the present case.

Similarly, in *New Hampshire v. Ramsey*, 366 F.3d 1 (1st Cir. 2004), on which BPMC relies for the proposition that a State's waiver can survive a dismissal without prejudice, the waiver was found in the same proceeding, not a separate action. In *Ram-*

sey, the State of New Hampshire was sued in federal court for violation of federal law and moved to dismiss the suit for failure to exhaust statutorily-required administrative remedies. *Id.* at 9. The State did not assert Eleventh Amendment immunity in that initial suit. *Id.* The district court dismissed the suit without prejudice for failure to exhaust, and the parties, including the State, proceeded to engage in the statutorily-provided administrative remedies. *Id.* at 10-12. The State did not assert Eleventh Amendment immunity until two years into the administrative remedy process, after it had already filed an unsuccessful motion to dismiss on other grounds. *Id.* at 12. When a federal arbitration panel found in favor of the plaintiffs on the merits of the case (without considering the Eleventh Amendment argument), the State filed suit in federal court challenging the ruling on the basis of the Eleventh Amendment. *Id.* at 13-14. The federal district court largely affirmed the arbitration panel's award, finding that the State had waived its immunity by its litigation conduct. *Id.* at 14.

On appeal, the First Circuit affirmed the district court's decision in part, holding that the State had waived its immunity as to injunctive relief by its litigation conduct, but not as to money damages (waiver as to money damages is discussed infra at n.6). *Id.* at 15. As to the claim for injunctive relief, the court held that, "[b]y invoking [the applicable] procedures (knowing that those procedures ultimately provided for federal judicial review) to obtain dismissal of a claim for injunctive relief, and then participating in the administrative process, the state has waived any immunity it may have to a federal forum and prospective equitable relief." *Id.* at 16. Framing its decision in the terminology of *Lapides*, on which the

First Circuit relied heavily, it explained that, "[i]n essence, the state voluntarily invoked the jurisdiction of a federal agency . . . and the federal courts in review of the agency determination, including their power to grant prospective equitable relief, even though it was not formally the plaintiff in the administrative proceeding." *Id.*

Ramsey, therefore, is a relatively straightforward application of *Lapides* that does not support BPMC's position in this case. In *Ramsey*, the State's initial waiver of immunity in the first suit, which was dismissed for failure to exhaust administrative remedies, had very little to do with the court's ultimate conclusion that the State waived its immunity when it invoked the statutorily-provided administrative remedies. *Id.* ("This case goes well beyond a simple matter of failure to raise an immunity argument in earlier proceedings."). Instead, it was the voluntary invocation of an administrative process that provided for federal judicial review that was the critical act amounting to waiver of immunity. Like the removal in *Lapides*, that initial voluntary invocation of the administrative remedies was found to constitute waiver of immunity. Beyond that initial invocation, *Ramsey* is similar to *Vas-Cath* in that the process invoked by the State was one continuous proceeding that included the jurisdiction of a federal agency followed by federal judicial review. *See id.* at 16 ("The state voluntarily put itself in the position of being a party in a federal administrative forum whose actions would be reviewed in federal court. The state's actions expressed a clear choice to submit its rights for adjudication in the federal courts."); *Vas-Cath*, 473 F.3d at 1383-84 ("The University's recourse to the PTO tribunal for adjudication of its claim . . . negates the assertion of immunity to bar appeal of that adjudication."). Accordingly, like *Lapides*, *Gunter*, and *Vas-Cath*, *Ramsey* only involves the application of a State's waiver of immunity in the same continuous proceeding, and does not support BPMC's arguments in the case at bar.[6]

In contrast, where a waiver of immunity occurs in an earlier action that is dismissed, or an entirely separate action, courts, including our own, have held that the waiver does not extend to the separate lawsuit. *See Tegic*, 458 F.3d at 1342-43 (discussed below); *City of S. Pasadena*, 284 F.3d at 1157-58. In *City of S. Pasadena*, relied upon by the district court in this action and described above, the dismissal without prejudice was found to prevent the "carry over" of an earlier waiver to a new lawsuit. *City of S. Pasadena*, 284 F.3d at 1157-58. Likewise, in *Tegic*, this court held that a State university's participation in one lawsuit did not amount to a waiver of immunity in a separate lawsuit, even one involving the same patent. 458 F.3d at 1342-43.

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[6] At oral argument, counsel for BPMC took issue with the comparison of *Ramsey* to *Vas-Cath*. Counsel argued that the initial waiver in the (dismissed) lawsuit in *Ramsey* was relevant to the First Circuit's holding, as evidenced by the fact that the First Circuit held that New Hampshire waived immunity as to injunctive relief (which the State failed to raise in the initial lawsuit), but not as to monetary damages (which the State made passing reference to in the initial lawsuit). According to counsel for BPMC, it was critical that the State in *Ramsey* failed to raise immunity as to claims for injunctive relief, the only claims in that initial lawsuit, but that it "alluded" to immunity from money damages in its motion to dismiss. We reject that reading of *Ramsey*. If anything, the First Circuit's finding that the State retained immunity from money damages represents a very narrow application of the waiver doctrine. In *Ramsey*, the State alluded to, but did not expressly assert, immunity from money damages in the first suit, failed to raise the defense of immunity until almost two years into the administrative remedies phase, and then invoked the jurisdiction of a federal district court to review the arbitration panel's decision. *Ramsey* does not stand for the proposition that a waiver of immunity can survive a dismissal without prejudice, as BPMC contends; rather, it stands for the proposition that the mere allusion to immunity from money damages in an earlier suit will preserve immunity, even after a State voluntarily invokes the jurisdiction of a federal agency and belatedly asserts immunity in that forum. Such a conservative approach to a State's waiver of sovereign immunity does not support BPMC's argument in this case. To the contrary, it cuts against it.

In *Tegic*, the University of Texas filed suit in federal court in the Western District of Texas against forty-eight cell phone companies alleging infringement of a patent it owned. *Id.* at 1337. Tegic, a Washington corporation, was not sued by the University but sold and licensed the allegedly infringing software to thirty-nine of the forty-eight defendants sued in the Texas action. *Id.* Rather than seek to intervene in the Texas action, Tegic brought a separate declaratory judgment action against the University in federal court in the Western District of Washington. *Id.* The University successfully moved to dismiss the Washington action on several grounds, including Eleventh Amendment immunity. *Id.* at 1338-39. This court affirmed dismissal of the case on the ground that it was barred by the University's Eleventh Amendment immunity, holding that the University's waiver as to the Texas suit did not extend to the suit by Tegic in Washington. *Id.* at 1342, 1345. We explained that, in waiving immunity in the Texas suit, the University "did not thereby voluntarily submit itself to a new action brought by a different party in a different state and a different district court." *Id.* at 1343. We also addressed the principle of waiver by litigation conduct, stating that, "[w]e agree with the

University that its filing of the Texas action did not establish waiver as to this separate action. While waiver in the litigation context focuses on the litigation act, the waiver must nonetheless be 'clear.'" *Id.* (citing *Lapides*, 535 U.S. at 620). Our holding in *Tegic*, therefore, demonstrates that a State's waiver of immunity as to the subject matter of a lawsuit does not, by itself, constitute a waiver of immunity in any future lawsuit involving that subject matter, as BPMC seems to argue it should in the present case.

By distinguishing *Lapides*, *Gunter*, *Vas-Cath*, and *Ramsey*, on one hand, and *City of S. Pasadena* and *Tegic*, on the other, we do not mean to draw a bright-line rule whereby a State's waiver of sovereign immunity can never extend to a re-filed or separate lawsuit. We note only that the case law relied upon by BPMC does not support its contention that waiver of immunity in one suit should extend to a separate action simply because the action involves the same parties and same subject matter. Indeed, two relevant principles we can extract from these cases are that a State's waiver of immunity generally does not extend to a separate or re-filed suit, and that, as we reaffirmed in *Tegic*, even a waiver by litigation conduct must nonetheless be "clear." These principles, of course, are related, as a waiver that does not "clearly" extend to a separate lawsuit generally would not preclude a State from asserting immunity in that separate action. With those principles in mind, we address BPMC's arguments that the policy behind the rule governing waiver by litigation conduct -- the need to avoid unfairness and inconsistency – should prevent DHS from asserting sovereign immunity in this case.

In *Lapides*, the Supreme Court explained that the rule governing waiver of immunity by litigation conduct rests on the need to avoid "unfairness" and "inconsistency," as well as to prevent a State from selectively using immunity to achieve a litigation advantage. *Lapides*, 535 U.S. at 620. Indeed, in *Lapides*, the State recognized that a state statute had waived sovereign immunity from state-law suits in state court, yet sought to invoke the jurisdiction of the federal court only to shield itself from liability that may otherwise attach in state court. *Id.* at 616. The concerns of unfairness and inconsistency, therefore, were clearly present in that case. These same concerns were also evident in both *Vas-Cath* and *Ramsey*, where the States stood to gain a significant tactical advantage in their selective use of immunity. In *Vas-Cath*, for example, the State initiated PTO proceedings, won a favorable ruling, and then sought to use its immunity to shield the favorable ruling from review in federal court. 473 F.3d at 1379-80. In *Ramsey*, the State successfully argued that the plaintiffs were required to exhaust administrative remedies, participated in the administrative process for almost two years, and then sought to shield itself from the unfavorable results from that process. 366 F.3d at 9-13. It is easy to see why in those cases, the courts cautioned that "[t]he principles of federalism are not designed for tactical advantage," *Vas-Cath*, 473 F.3d at 1383, and that "[t]o permit the state to reverse course would contravene the reasons for the doctrine of waiver by litigation conduct recognized by *Lapides* . . .," *Ramsey*, 366 F.3d at 16-17.

The same considerations of "unfairness" and "inconsistency" expressed in *Lapides*, *Vas-Cath*, and *Ramsey* simply are not present in the case at bar. BPMC complains that, if DHS is permitted to assert immunity in this lawsuit, DHS will gain an unfair tactical advantage because parties like BPMC will be forced either to litigate in improper venues or face the consequence of moving to dismiss, which includes risking the possibility that the State will assert immunity in a re-filed action. BPMC also argues that, as a side benefit of its unfair tactics, DHS will gain the benefit of initial disclosures under Fed. R. Civ. P. 26 before a court can rule on any motion to dismiss for improper venue.

The concerns BPMC cites hardly rise to the level of those present in *Lapides*, *Vas-Cath*, or *Ramsey*. First, it is unlikely that venue considerations alone would govern a State's decision to assert sovereign immunity from a given lawsuit. Second, it defies common sense that a State keen on retaining its sovereign immunity would, as BPMC posits, risk subjecting itself to liability merely to obtain initial disclosures, hoping that the defendant will object to the chosen venue, which is, of course, a waivable defense. *See* Fed. R. Civ. P. 12(h)(1). Finally, BPMC ignores the fact that these concerns are not even present in this case, both because DHS did not choose the forum of the 1997 lawsuit - it intervened in ongoing litigation – and because the current action was initiated in that same venue. Therefore, the concerns of "unfairness" and "inconsistency" raised by BPMC simply are not the types of concerns that should preclude DHS from asserting immunity in this case.

In sum, we conclude that any unfairness or inconsistency that would arise from permitting DHS to assert sovereign immunity in the present case is not so substantial as to cause us to diverge from the general principles of waiver that we have laid out in this opinion: that a waiver generally does not extend to a separate lawsuit, and that any waiver, including one effected by litigation conduct, must be "clear." Accordingly, we reject BPMC's first theory as to why DHS should be prevented from asserting sovereign immunity in this case.

B

Next, BPMC argues that DHS should be judicially estopped from asserting immunity because DHS's current position is inconsistent with its position in the 1997 lawsuit, where, in its motion to intervene, it asserted that it was a party over which the court had jurisdiction. Because judicial estoppel is not a matter unique to our jurisdiction, we look to Ninth Circuit law to address this issue. *Minn. Mining & Mfg. Co. v. Chemque, Inc.*, 303 F.3d 1294, 1302 (Fed. Cir. 2002) (citing *Wang Labs., Inc. v. Applied Computer Scis., Inc.*, 958 F.2d 355, 358 (Fed. Cir. 1992)). A district court's decision not to invoke judicial estoppel is reviewed for abuse of discretion. *Engquist v. Or. Dept. of Agric.*, 478 F.3d 985, 1000 (9th Cir. 2007).

The doctrine of judicial estoppel provides that "[w]here a party assumes a certain position in a legal proceeding, and succeeds in maintaining that position, he may not thereafter, simply because his interests have changed, assume a contrary position, especially if it be to the prejudice of the party who has acquiesced in the position formerly taken by him." *New Hampshire v. Maine*, 532 U.S. 742, 749 (2001) (quoting *Davis v. Wakelee*, 156 U.S. 680, 689 (1895)). The purpose of the doctrine is "to protect the integrity of the judicial process by prohibiting parties from deliberately changing positions according to the exigencies of the moment." *Id.* at 749-50 (internal citations and quotations omitted).

The Supreme Court has identified three factors to consider in determining whether the doctrine applies, but the Court explained that these factors are not "inflexible prerequisites" or an "exhaustive formula." *Id.* at 750-51. Those factors are (1) whether a party's later position is "clearly inconsistent" with its earlier position; (2) whether the party succeeded in persuading a court to accept that party's earlier position, so that judicial acceptance of an inconsistent position in a later proceeding would create "the perception that either the first or second court was misled;" and (3) whether the party seeking to assert an inconsistent position would derive an unfair advantage or impose an unfair detriment on the opposing party if not estopped. Id.

In this case, the district court found that the second and third factors were present - i.e., it found that DHS affirmatively asserted that the court had jurisdiction over its claims in the 1997 action, an assertion which that court accepted; and DHS would obtain a significant advantage by asserting sovereign immunity in that it would be entitled to absolute immunity from monetary damages. *Biomedical Patent Mgmt. Corp.*, 2006 WL 1530177, at *6. The district court concluded, however, that DHS's positions were not clearly inconsistent because of the "substantial intervening change in federal law" brought about by the Supreme Court's decision in *Florida Prepaid, see supra* Part I.B, which was issued between the 1997 lawsuit and the present action. *Id.* Specifically, when DHS intervened in the 1997 lawsuit, it was not settled whether DHS was entitled to assert a sovereign immunity defense in a suit for patent infringement, but after *Florida Prepaid*, it became clear that DHS was entitled to assert such a defense. *Id.* As such, the district court concluded that

DHS's differing approaches with respect to asserting its sovereign immunity simply mirrored the change in the law, and they could not be characterized as "clearly inconsistent." *Id.* The district court thus found that DHS was not judicially estopped from asserting immunity in this case. Id.

BPMC argues that the district court abused its discretion in reaching its conclusion because DHS's positions were, in fact, clearly inconsistent, and because *Florida Prepaid* did nothing to change the well-established principle that intervention in a lawsuit constitutes a waiver of immunity. As to BPMC's first point, we do not find that the district court abused its discretion. Perhaps it is more precise to say that, although DHS's positions were inconsistent, the inconsistency is excused by an intervening change in the law. *See Maui Land & Pineapple Co. v. Occidental Chem. Corp.*, 24 F.Supp.2d 1083, 1086 (D. Haw. 1998) (explaining that the application of judicial estoppel is "inappropriate when a party is merely changing its position in response to a change in the law." (citing *Arizona v. Shamrock Foods Co.*, 729 F.2d 1208, 1215 (9th Cir. 1984))). The end result, however, is the same, and DHS is not judicially estopped from asserting a new position that resulted from a change in the law.

In addition, we reject BPMC's argument that there was not actually a change in the law as it relates to DHS's actions because *Florida Prepaid* did nothing to change the well-established principle that intervention in a lawsuit constitutes a waiver of immunity. In 1997, the validity of Congress' abrogation of state sovereign immunity in the Patent Remedy Act had not yet been considered by the Supreme Court. At that time, DHS could not expect to succeed on a defense of sovereign immunity if sued by BPMC, putting it in the position having nothing to lose by intervening in the 1997 lawsuit, and potentially much to gain by seeking to prevent an adverse result which could affect its interests. The issuance of *Florida Prepaid* put DHS in a much different position. After *Florida Prepaid*, DHS could be confident that, if sued, it could assert a defense of sovereign immunity, which is precisely what it did. Accordingly, we reject BPMC's argument that *Florida Prepaid* did not effect a change in the law relevant to this case.

BPMC asks that we ignore the change brought on by *Florida Prepaid* in our analysis because, it asserts, that case was not likely the driving force behind DHS's changing sovereign immunity posture. In support of this point, BPMC notes that, in the 1998 lawsuit, which was filed five days after the 1997 lawsuit was dismissed but before the Supreme Court decided *Florida Prepaid*, DHS asserted the affirmative defense of Eleventh Amendment sovereign immunity. Clearly, the differing position between the 1997 lawsuit and the 1998 lawsuit cannot be explained by a change in the law because none had occurred at that time.

This court, however, is not asked to assess whether any unfairness would arise from DHS's decision to assert sovereign immunity in connection with the 1998 action. The question here is whether it is fundamentally unfair to allow DHS to assert its immunity in this 2006 lawsuit solely because it chose to intervene in a related action almost ten years earlier; we conclude it is not.

We find that the district court correctly determined that DHS is not judicially estopped from asserting sovereign immunity in the present lawsuit, and did not abuse its discretion by dismissing this action in the face of BPMC's argument to the contrary.

C

BPMC also argues that the conduct of the State of California in the patent system, and particularly patent litigation, operates as a general waiver for all California State defendants participating in patent suits. This argument merits little discussion.

The Supreme Court in *Coll. Sav. Bank* expressly overruled prior case law supporting the notion BPMC urges – i.e., that a state can constructively waive its Eleventh Amendment immunity by its participation in a regulatory scheme. 527 U.S. at 680 ("We think that the constructive-waiver experiment of *Parden* was ill conceived, and see no merit in attempting to salvage any remnant of it."); *see also Vas-Cath*, 473 F.3d at 1381 ("It is established that a state's participation in the federal patent system does not of itself waive immunity in federal court with respect to patent infringement by the state . . ."). This argument, therefore, must be rejected.

D

Finally, BPMC argues that a recent Supreme Court decision, *Central Virginia Community Coll. v. Katz*, 546 U.S. 356, 126 S.Ct. 990 (2006), implicitly overruled *Florida Prepaid* such that sovereign immunity is no longer available in patent infringement actions. BPMC raises this issue on appeal, however, only to "preserve[] it for potential Supreme Court review." The holding in Katz was so closely tied to the history of the Bankruptcy Clause and the unique aspects of bankruptcy jurisdiction that it cannot be read to extend to actions for patent infringement.

See, e.g., *Katz*, 546 U.S. at 378, 126 S.Ct. at 1005 ("In ratifying the Bankruptcy Clause, the States acquiesced in a subordination of whatever sovereign immunity they might otherwise have asserted in proceedings necessary to effectuate the in rem jurisdiction of the bankruptcy courts."). Because we find that *Katz* cannot be read to overrule *Florida Prepaid*, either expressly or implicitly, we find that the district court correctly rejected this argument.

III

For the foregoing reasons, we find that DHS is not precluded from asserting Eleventh Amendment sovereign immunity in this case. We, therefore, affirm the decision of the district court.

AFFIRMED

Each party shall bear its own costs.

APPENDIX B

UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF CALIFORNIA

No. C 06-00737 MHP

BIOMEDICAL PATENT MANAGEMENT CORP.,
a California Corporation,
Plaintiff

v.

STATE OF CALIFORNIA, DEPARTMENT OF HEALTH
SERVICES, an arm of the State of California,
Defendant

MEMORANDUM & ORDER
Re: Motion to Dismiss

Marilyn Hall Patel, District Judge
Filed June 9, 2006

Plaintiff Biomedical Patent Management Corp. ("BPMC") filed this patent infringement lawsuit against defendant California Department of Health Services ("DHS"). Now before the court is DHS's motion to dismiss based on sovereign immunity under the Eleventh Amendment to the United States Constitution. Having considered the parties' arguments and submissions, and for the reasons set forth below, the court enters the following memorandum and order.

BACKGROUND[1]

BPMC is the holder of United States Patent No. 4,874,693 (the '693 patent), covering a method of prenatal screening for fetal chromosomal abnormalities. DHS operates a prenatal screening program that allegedly makes use of the method claimed in the '693 patent.

The parties have engaged in previous litigation under the '693 patent that is relevant to defendant's motion to dismiss. On August 28, 1997 Kaiser Foundation Health Plan, Inc. filed a declaratory judgment action against BPMC in the Northern District of California, seeking a declaration that Kaiser did not infringe any valid or enforceable claim of the '693 patent. DHS filed a motion to intervene on September 30, 1997, seeking a similar declaration. Plaintiff's Request for Judicial Notice ("Plaintiff RJN"), Exh. 1. The court granted DHS's motion to intervene, and DHS filed a complaint in intervention on December 15, 1997. *Id.*, Exh. 2. BPMC subsequently filed counterclaims for patent infringement against both Kaiser and DHS, which DHS answered on April 8, 1998. *Id.*, Exhs. 3-4. The 1997 action was ultimately dismissed without prejudice on May 6, 1998 for improper venue.

Just six days later, on May 12, 1998 BPMC filed a lawsuit against DHS in the Southern District of California, again alleging infringement of the '693 patent. Defendant's Request for Judicial Notice ("Defendant RJN"), Exh. 1. DHS answered on June 5, 1998, but asserted an affirmative defense based on

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[1] Unless otherwise noted, background facts are taken from plaintiff's complaint.

Eleventh Amendment sovereign immunity. *Id.*, Exh. 2 ¶ 19.

On June 30, 1998 the Federal Circuit decided *Florida Prepaid Postsecondary Education Expense Board v. College Savings Bank*, 148 F.3d 1343 (Fed. Cir. 1998), *rev'd*, 527 U.S. 627 (1999). In *Florida Prepaid*, the Federal Circuit held that Congress validly abrogated state sovereign immunity to patent infringement lawsuits. *Id.* at 1355. Florida promptly petitioned for certiorari.

On October 8, 1998, BPMC sought to dismiss the Southern District lawsuit without prejudice under Federal Rule of Civil Procedure 41(a)(2). Defendant RJN, Exh. 8. In requesting dismissal, BPMC noted the large number of Eleventh Amendment cases, including *Florida Prepaid*, then pending before the Supreme Court. *See id.* at 2, 5-7 (citing *College Sav. Bank v. Florida Prepaid Postsecondary Educ. Expense Bd.*, 131 F.3d 353 (3d Cir. 1997), *aff'd*, 527 U.S. 666 (1999); *Chavez v. Arte Publico Press*, 139 F.3d 504 (5th Cir. 1998), vacated en banc, 180 F.3d 674 (5th. Cir 1999); and *Florida Prepaid*, 148 F.3d at 1343). BPMC argued that it would serve the interests of judicial economy to wait for the law of sovereign immunity to be clarified. *Id.*

The court granted BPMC's motion to dismiss on November 20, 1998, noting that voluntary dismissal without prejudice under Rule 41(a)(2) should be liberally granted unless it will harm the defendant. *Id.*, Exh. 11 at 5. The court found that DHS would not be harmed by the dismissal, as the discovery exchanged by the parties would continue to be useful in a future lawsuit. Because the court found that DHS would not be harmed, it dismissed the case without prejudice. *Id.* at 5. The court also noted that "[a]lthough not required to do so, BPMC has provided a valid reason for the dismissal"—namely, the unresolved status of DHS's sovereign immunity defense. *Id.* at 4.

The Supreme Court granted certiorari in *Florida Prepaid* on January 8, 1999 and subsequently ruled on June 23, 1999 that Congress lacks authority to abrogate state sovereign immunity under Article I of the Constitution, and that Congress's attempt to abrogate immunity to patent infringement lawsuits exceeded the scope of its authority under the Fourteenth Amendment. *Florida Prepaid Postsecondary Educ. Expense Bd. v. College Sav. Bank*, 527 U.S. 627 (1999). In a companion case decided the same day, the Court abrogated the constructive waiver doctrine, under which a state entity may implicitly waive its sovereign immunity by voluntarily participating in a federally regulated activity. *College Sav. Bank*, 527 U.S. at 680 (overruling *Parden v. Terminal R. of Ala. Docks Dept.*, 377 U.S. 184 (1964)). The combined effect of *Florida Prepaid* and *College Savings Bank* was to prohibit patent infringement suits seeking monetary recovery from state entities absent an express waiver of immunity by the state.

Almost seven years after *Florida Prepaid* was decided, BPMC filed this lawsuit, once again alleging infringement of the '693 patent. DHS now moves to dismiss, arguing that it is immune from suit under the law as clarified in *Florida Prepaid* and *College Savings Bank*.

DISCUSSION

BPMC argues that DHS lacks sovereign immunity under four separate theories. First, BPMC contends that DHS's decision to intervene in the 1997 lawsuit serves as a waiver in the instant lawsuit, which involves the same parties and the same patent. Second, BPMC argues that DHS is judicially estopped from asserting immunity because the court accepted DHS's jurisdictional arguments in allowing DHS to intervene in the 1997 lawsuit. Third, BPMC argues that the State of California's large-scale participation in the patent system serves as a general waiver of immunity for all state defendants in patent infringement suits. Finally, BPMC argues that a Supreme Court decision issued this term, *Central Virginia Community College v. Katz*, 126 S. Ct. 990 (2006), implicitly overrules *Florida Prepaid*.

The court will consider each argument in turn.

I. Waiver Based on the 1997 Lawsuit

DHS concedes that its intervention in the 1997 lawsuit was a waiver of immunity with respect to that lawsuit, including BPMC's compulsory patent infringement counterclaims. *See* Defs.' Reply Brief at 5; *Regents of the Univ. of N.M. v. Knight*, 321 F.3d 1111, 1126 (Fed. Cir.), *cert. denied sub nom Scallen v. Regents of the Univ. of N.M.*, 540 U.S. 820 (2003) ("when a state files suit in federal court to enforce its claims to certain patents, the state shall be considered to have consented to have litigated in the same forum all compulsory counterclaims.").

The parties disagree, however, as to whether DHS's waiver in the 1997 lawsuit extends to this lawsuit. BPMC argues that waiver of immunity in a prior lawsuit serves as a waiver with respect to subsequent suits concerning the same matter, and that this lawsuit, which involves the same parties, patent, and accused conduct as the 1997 lawsuit, is within the scope of the 1997 waiver. DHS counters that its assertion of sovereign immunity in the 1998 lawsuit, coupled with BPMC's failure to argue waiver of immunity in that case, permits DHS to assert sovereign immunity as a defense in this lawsuit.

As a threshold matter, the court must determine which body of waiver law to apply. This patent lawsuit falls within the appellate jurisdiction of the Federal Circuit, which applies its own law when necessary to "promot[e] national uniformity in patent law." *Knight*, 321 F.3d at 1124. In *Knight*, the Federal Circuit held that questions of Eleventh Amendment waiver in a patent infringement lawsuit are governed by Federal Circuit law. This court will therefore apply Federal Circuit law, to the extent that it exists, in determining whether DHS's previous waiver extends to this lawsuit.

The Federal Circuit has held that the effect of a voluntary dismissal "is to render the proceedings a nullity and leave the parties as if the action had never been brought." *Graves v. Principi*, 294 F.3d 1350, 1356 (Fed. Cir. 2002); *Bonneville Assocs. Ltd. P'ship v. Barram*, 165 F.3d 1360, 1364 (Fed. Cir.), *cert. denied*, 528 U.S. 809 (1999). Thus, a party who dismisses an appeal without prejudice after the applicable filing period has lapsed loses the ability to refile the appeal at a later date. *Graves*, 294 F.3d at 1356.

The Federal Circuit has not ruled on the precise question currently before the court: whether dismissal without prejudice of a lawsuit has the effect of negating any waiver of sovereign immunity made during the course of that lawsuit. This court therefore turns to Ninth Circuit law, which embraces precisely the same rule as the Federal Circuit for dismissals without prejudice. *See Navellier v. Sletten*, 262 F.3d 923, 938 (9th Cir. 2001), *cert. denied sub* *nom McLachlan v. Simon*, 536 U.S. 941 (2002) ("A dismissal without prejudice pursuant to Rule 41(a)(2) leaves the parties where they would have stood had the lawsuit never been brought." (quoting *In re Corey*, 892 F.2d 829, 835 (9th Cir. 1989), *cert. denied*, 498 U.S. 815 (1990))); *Concha v. London*, 62 F.3d 1493, 1506 (9th Cir. 1995), *cert. dismissed*, 517 U.S. 1183 (1996) (a dismissal without prejudice "leaves the parties as though no action had been brought.").

The Ninth Circuit considered the significance of a waiver of sovereign immunity in a previous lawsuit that was dismissed without prejudice in *City of South Pasadena v. Mineta*, 284 F.3d 1154 (9th Cir. 2002). In *City of South Pasadena*, the plaintiff originally sued the state of California in 1973 to prevent construction of a freeway through South Pasadena. *Id.* at 1155. The parties stayed the litigation pending final approval of the freeway plans by federal and California authorities. *Id.* When final approval was granted in 1998, the plaintiff sought leave to amend its complaint in order to add new parties and claims which arose during the period between 1973 and 1998. The district court refused to permit amendment, and the parties stipulated to dismissal without prejudice of the 1973 lawsuit. *Id.* at 1156. Plaintiff then filed a new lawsuit, asserting a mixture of old and new claims. *Id.* The State of California asserted a sovereign immunity defense. *Id.* The district court found that California had waived its sovereign immunity through its voluntary participation during the twenty-five-year pendency of original federal litigation. *Id.*

The Ninth Circuit reversed, holding that Federal Rule of Civil Procedure 41(a)(1), which provides for voluntary dismissal, "disallows the carry-over of any waivers from a voluntarily dismissed action to its reincarnation." *Id.* at 1158. The effect of a dismissal without prejudice is to "leave[ ] the situation as if the action never had been filed." *Id.* at 1157 (citing 9 Charles Alan Wright & Arthur R. Miller, *Federal Practice and Procedure* § 2367, at 321 (2d ed.1995)). Because the first federal action was dismissed without prejudice under Rule 41(a)(1), the state defendants were entitled to assert sovereign immunity in the second action despite having waived immunity in the first. *Id.* at 1158 ("Because the state promptly raised the immunity defense against state law claims in the current litigation, and because these claims are undisputably of the type barred by the Eleventh Amendment, the district court erred in failing to dismiss them."); *cf. id.* at 1157 ("By failing to invoke the immunity defense during the pendency of the 1973 action, the state waived it.").

Here, as well, DHS wishes to assert sovereign immunity in this lawsuit despite having waived it in the 1997 lawsuit. The 1997 lawsuit in this case differs from the 1973 lawsuit in *City of South Pasadena* in only one material respect: it was dismissed involuntarily for lack of proper venue pursuant to Rule 41(b) rather than voluntarily pursuant to Rule 41(a). Rule 41(b), however, provides for dismissal "without prejudice" in certain circumstances, such as "for improper venue." Fed. R. Civ. P. 41(b). Courts and commentators have consequently interpreted a dismissal without prejudice under Rule 41(b), like a dismissal without prejudice under Rule 41(a), to "leave[ ] the situation as if the action never had been filed." *See* 9 Charles Alan Wright & Arthur R. Miller, *Federal Practice and Procedure* § 2373 n.8 (2d ed.1995) (noting that "[d]ismissal without prejudice [under Rule 41(b)] leaves the situation as if the suit never had been brought." (citing *Bomer v. Ribicoff*, 304 F.2d 427 (6th Cir. 1962))); 8-41 *Moore's Federal Practice - Civil* § 41.50 ("When the district court elects to dismiss an action without prejudice under Rule 41(b), the dismissal leaves the parties in the same legal position as if no suit had been filed."); *Hilbun v. Goldberg*, 823 F.2d 881, 883 (5th Cir. 1987), *cert. denied*, 485 U.S. 962 (1988) ("A federal court that dismisses without prejudice a suit arising from a federal statutory cause of action has not adjudicated the suit on its merits, and leaves the parties in the same legal position as if no suit had ever been filed."). The reasoning of the Ninth Circuit in *City of South Pasadena* is thus equally applicable in the Rule 41(b) context.

The cases cited by BPMC in support of its argument that DHS is bound by its waiver in the 1997 lawsuit are not applicable. In *Lapides v. Board of Regents of the University System of Georgia*, the plaintiff brought a lawsuit against an arm of the state of Georgia in state court. 535 U.S. 613, 616 (2002). The state then removed to federal court and simultaneously moved to dismiss based on Eleventh Amendment immunity. *Id.* The Supreme Court held that Georgia waived its immunity by removing to federal court. *Id.* at 624. In reaching that conclusion, the Court noted that to rule otherwise could generate "seriously unfair results" by allowing states to selectively invoke or deny federal jurisdiction in order to achieve tactical litigation advantage. *Id.* at 619. Lapides is not applicable in this case because, as discussed above, the waiver took place in a previous action which was dismissed without prejudice. The state has not waived its immunity through invocation of federal jurisdiction in this action.

Plaintiff cites *Gunter v. Atlantic Coast Line Railroad Co.*, 200 U.S. 273 (1906) in support of its argument that the previous waiver should extend to this lawsuit. In *Gunter*, a railroad company shareholder had previously sued the state of South Carolina to prevent the collection of taxes levied against the railroad. South Carolina participated in the original lawsuit without objection. *Id.* at 278. The shareholder prevailed, and the court entered an injunction preventing the state from collecting the taxes. *Id.* at 278-79. Twenty-five years then elapsed, during which the state made no attempt to collect the taxes. *Id.* at 279. When the state again attempted to do so, the railroad filed a petition in federal court seeking to enforce the previous injunction. *Id.* at 281-82. The state argued that, under the Eleventh Amendment, the federal court lacked jurisdiction to enforce the injunction. *Id.* at 291. The Supreme Court disagreed, holding that a federal court has jurisdiction when "acting in a manner ancillary to a decree rendered in a cause over which it had jurisdiction." *Id.* at 292. In *Gunter*, unlike in the instant case, the plaintiff was suing to enforce a "decree rendered in a cause over which [the federal courts] had jurisdiction"—i.e., the injunction entered in the original case. *See id.* Here, in contrast, the original case did not result in a final decision with preclusive effect. Rather, it was dismissed without prejudice.

The court therefore finds that DHS has not waived its sovereign immunity in this suit solely because it waived immunity in the 1997 lawsuit, which was dismissed without prejudice.

II. Judicial Estoppel

DHS's conduct in the 1997 lawsuit, however, went beyond mere waiver. It actively asserted federal jurisdiction in order to intervene in the lawsuit. The court accepted DHS's argument and permitted it to intervene. BPMC claims that the court's acceptance of DHS's argument raises a judicial estoppel which prevents DHS from asserting immunity in this case.

"Judicial estoppel is a flexible equitable doctrine that encompasses a variety of abuses, one form of which is preclusion of inconsistent positions that estops a party from gaining an advantage by taking one position and then seeking another advantage from an inconsistent position." *In re Cheng*, 308 B.R. 448, 452 (B.A.P. 9th Cir. 2004). Although judicial estoppel is an equitable doctrine that is not easily defined, the United States Supreme Court has identified three factors that are relevant to the application of the doctrine. *New Hampshire v. Maine*, 532 U.S. 742, 750 (2001). First, a party's position in the second matter must be "clearly inconsistent" with its position in the first matter. *Id.* Second, a court must have accepted the party's earlier position. *Id.* at 750-751 (noting that a party's inconsistent position does not pose a threat to judicial integrity unless accepted). The third consideration is whether the party asserting an inconsistent position "would derive an unfair advantage or impose an unfair detriment on the opposing party if not estopped." *Id.* at 751.

It is not disputed that DHS affirmatively asserted that the court had jurisdiction over its declaratory relief claims in the 1997 action, and that the court accepted DHS's argument. It is also not disputed that DHS will obtain a significant advantage—absolute immunity from monetary damages—by asserting sovereign immunity in this suit.

The problem with applying judicial estoppel in this case is that DHS's position in the 1997 litigation is not clearly inconsistent with its position in this case, given the substantial intervening change in federal law. When the 1997 lawsuit commenced, it was not settled whether DHS was entitled to assert a sovereign immunity defense. Only in 1999, after the Supreme Court decided *Florida Prepaid*, did the defense of sovereign immunity clearly apply to patent lawsuits. DHS's change in position mirrors this change in the law. DHS is therefore not precluded from asserting immunity in this case.[2]

III. California's Exploitation of the Patent System

BPMC next argues that California's "massive exploitation of the patent system," particularly through the University of California, serves as a general waiver of immunity with respect to patent infringement actions. DHS counters that it is a separate branch of the state and should not be bound by the choices of other state agencies to participate in large-scale patent prosecution and litigation. DHS also claims that BPMC is attempting to revive so-called constructive waiver doctrine which was abrogated by the Supreme Court in *College Savings Bank*.

The court is indeed troubled by the University of California's ability to reap the benefits of the patent system without being exposed to liability for infringement. Similarly situated private universities enjoy no such advantage. Regardless of the wisdom of the currently governing law, however, the law is clear: a state entity remains immune from lawsuit even "where a State runs an enterprise for profit, operates in a field traditionally occupied by private persons or corporations, engages in activities sufficiently removed from 'core [state] functions,' . . . or otherwise acts as a 'market participant' in interstate commerce." *College Savings Bank*, 527 U.S. at 680. BPMC's description of California's participation in the patent system falls squarely under the rubric of constructive waiver which was rejected when the *College Savings Bank* court overruled *Parden*.

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[2] As the court finds that judicial estoppel does not bar DHS's immunity defense, it need not reach DHS's separate contention that BPMC's failure to raise its waiver argument in the 1998 litigation precludes it from doing so now.

The fact that California actually waived immunity by pursuing past patent lawsuits—including the predecessor to the instant lawsuit—does not serve as an express waiver of immunity in this lawsuit.

IV. The Effect of Katz

Finally, BPMC argues that the Supreme Court implicitly overruled *Florida Prepaid* and *College Savings Bank* in *Katz*, decided this term. The holding in *Katz* is carefully circumscribed, however, and does not extend beyond the realm of federal bankruptcy law, which the Supreme Court apparently regards as *sui generis* based on the history of the Bankruptcy Clause. *Katz*, 126 S. Ct. at 1004 ("The ineluctable conclusion, then, is that States agreed in the plan of the Convention not to assert any sovereign immunity defense they might have had in proceedings brought pursuant to "Laws on the subject of Bankruptcies."). The court carefully distinguished previous Article I sovereign immunity decisions such as *Seminole Tribe of Fla. v. Florida*, 517 U.S. 44 (1996) based on the peculiar *in rem* nature of bankruptcy proceedings. *Id.* at 1000 ("Bankruptcy jurisdiction, as understood today and at the time of the framing, is principally *in* *rem* jurisdiction."). Although the dissent in *Katz* criticized the majority for "cast[ing] aside" the "settled doctrine" that Article I of the Constitution does not provide Congress with the authority to abrogate sovereign immunity, *see id.* at 1005-06 (Thomas, J., dissenting), the majority did not mention *Florida Prepaid* or *College Savings Bank* at all, much less overrule them. While *Katz* may signal a retreat from the rigid distinction between Congressional authority under Article I and the Fourteenth Amendment, BPMC's interpretation of the decision is far broader than its actual language will permit.

CONCLUSION

For the foregoing reasons, the court hereby GRANTS DHS's motion to dismiss BPMC's complaint without prejudice. BPMC may file an amended complaint if it chooses, naming appropriate parties and seeking appropriate relief, within 30 days of this order.

IT IS SO ORDERED.

Dated: June 5, 2006

s/Marilyn Hall Patel
MARILYN HALL PATEL
District Judge
United States District Court
Northern District of California

UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF CALIFORNIA

No. C 06-00737 MHP

BIOMEDICAL PATENT MANAGEMENT CORP.,
a California Corporation,
Plaintiff

v.

STATE OF CALIFORNIA, DEPARTMENT OF HEALTH SERVICES, an arm of the State of California,
Defendant

JUDGMENT
(Fed. R. Civ. P. 58)

This action having come before this court, the Honorable Marilyn Hall Patel, United States District Judge presiding, and the issues having been duly presented and an order having been duly filed on June 5, 2006, granting defendant's motion to dismiss and plaintiff having notified the court that it does not intend to seek amendment as allowed by the court's order and requesting that final judgment be entered,

IT IS ORDERED AND ADJUDGED that defendants' motion to dismiss is GRANTED and this action is DISMISSED in its entirety with prejudice.

Dated: June 9, 2006

s/Marilyn Hall Patel
MARILYN HALL PATEL
District Judge
United States District Court
Northern District of California

APPENDIX C

UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF CALIFORNIA

No. 98-CV-0897-K (JFS)

BIOMEDICAL PATENT MANAGEMENT CORPORATION,
Plaintiff

v.

STATE OF CALIFORNIA, DEPARTMENT OF
HEALTH SERVICES,
Defendants

ORDER GRANTING PLAINTIFF'S MOTION FOR A VOLUNTARY DISMISSAL WITHOUT PREJUDICE

Judith N. Keep, District Judge
Filed November 17, 1998

Plaintiff Biomedical Patent Management Corporation ("BPMC") moves to voluntarily dismiss the action against the State of California, Department of Health Services ("DHS"). Defendant DHS conditionally opposes. Both parties are represented by counsel.

I. Background

The following facts are taken primarily from the court's October 9, 1998 Order. On May 12, 1998, plaintiff Biomedical Patent Management Corporation filed a complaint against defendants Kaiser Foundation Health Plan and Kaiser Foundation Hospitals (collectively "Kaiser"), Case No. 98-CV-0881-K (JFS). On May 12, 1998, plaintiff filed a separate complaint against defendant State of California, Department of Health Services ("DHS"), Case No. 98-CV-0897-R (LAB). These cases were consolidated pursuant to this court's Order of October 9, 1998.

Plaintiff alleges that the defendant performs laboratory services and induces others to provide services which infringe its United States Patent 4,874,693 ("the '693 Patent"). Plaintiff is a California corporation with its principal place of business in San Diego, California. DHS is an agency of the State of California. Plaintiff asserts that on October 17, 1989, the United States Patent Office issued U.S. Patent 4,874,693 ("the '693 Patent"), entitled "Method for assessing placental dysfunction," to Mark Bogart, Ph.D. *See* DHS Complaint at ¶ 6. Plaintiff avers that it now owns and holds all rights to enforce the '693 Patent pursuant to assignment of those rights; consequently, plaintiff claims that it is solely entitled to recover for all acts of infringement. *See id.*

According to defendant DHS, the State of California initiated a state-wide public health program in 1986, implemented through DHS, to provide maternal blood screening that aids in assessing the risk that an expectant mother is carrying an abnormal fetus. In 1995, DHS allegedly adopted an improved blood screening test, sometimes referred to as "triple marker" screening. According to defendant, it uses competitively bid contracts with eight laboratories throughout California, including Kaiser, to perform certain services in connection with the screening.

Plaintiff argues that DHS is infringing on its exclusive rights under the '693 Patent. Plaintiff asserts four causes of action against DHS: 1) literal patent infringement; 2) patent infringement under the doctrine of equivalents; 3) literal patent infringement by inducement; and 4) patent infringement by inducement under the doctrine of equivalents.

On October 13, 1998, plaintiff filed its papers in support of its Motion for a Voluntary Dismissal Without Prejudice. On October 26, 1998, defendant DHS filed their Opposition, or in the Alternative, Conditional Non-Opposition. BPMC filed its Reply on November 6, 1998.

II. Standard of Law

"Federal Rule of Civil Procedure 41(a)(2) allows a plaintiff, pursuant to an order of the court, and subject to any terms and conditions the court deems proper, to dismiss an action without prejudice at any time." *Westlands Water Dist. v. U.S.*, 100 F.3d 94 (9th Cir. 1996) (citing Fed.R.Civ.P. 41(a)(2)). The purpose of Rule 41(a)(2) is to permit a plaintiff to dismiss an action without prejudice provided that the defendant will not be prejudiced or unfairly affected by the dismissal. *See Stevedoring Services of America v. Armilla Int'l B.V.*, 889 F .2d 919 (9th Cir. 1989). The decision whether to grant a 41(a)(2) dismissal is within the sound discretion of this court. *See Westlands Water Dist.*, 100 F.3d at 96. When ruling on a motion to dismiss without prejudice, the court must determine whether the defendant will suffer legal prejudice as a result of the dismissal. *See id.* "Legal prejudice is prejudice to some legal interest, some legal claim, some legal argument. Uncertainty because a dispute remains unresolved is not legal prejudice." *Id.* at 97. The inconvenience of defending another lawsuit is not considered legal prejudice either. *See Hyde & Drath v. Baker*, 24 F.3d 1162, 1169 (9th Cir. 1994).

III. Discussion

Plaintiff BPMC moves to voluntarily dismiss without prejudice the action it filed approximately six months ago. Though arguing that it is not required to provide any reason for its proposed dismissal, plaintiff states that dismissal without prejudice at this time may save both parties significant resources that could be wasted in litigation. Specifically, BPMC argues that a split in the circuits regarding the viability of Eleventh Amendment immunity for state actors, a defense alleged by DHS, may be resolved definitively by the Supreme Court. BPMC urges the court to await such a ruling before proceeding with this litigation.

The conflict in circuit law involves three cases. In *College Savings Bank v. Florida Prepaid Postsecondary Educ. Expense Bd.*, 131 F.3d 353 (3rd Cir. 1997), the Third Circuit held that the intellectual property claim of unfair competition under the Lanham Act falls within the scope of state immunity. In *Chavez v. Arte Publico Press*, 139 F.3d 504 (5th Cir. 1998), *revised and superseded by* 157 F.3d 282 (5th Cir. 1998), the Fifth Circuit reached the same conclusion in a copyright action. The Federal Circuit, in *College Savings Bank v. Florida Prepaid Postsecondary Educ. Expense Bd.*, 148 F.3d 1343 (Fed.Cir. 1998), split with the reasoning of the Third and Fifth Circuit. The Federal Circuit, in a patent context, held that Congress' statute could legitimately abrogate state immunity. *See id.* Petitions for certiorari to the Supreme Court have been filed, but the Supreme Court has yet to grant a petition for certiorari in any of the three cases.

BPMC argues that it wishes to avoid costly and lengthy litigation when the Supreme Court may grant certiorari and resolve a controlling legal issue in this case. BPMC states that two of the three petitions were filed on July 17, 1998 and September 28, 1998. Both of these dates occurred after BPMC filed its suit. The petition for the Federal Circuit was filed one week before BPMC brought the present motion. DHS argues that BPMC is motivated by a desire to avoid a definitive ruling on the patent issue. BPMC responds by stating:

> BPMC wishes to avoid extensive expenditures of the Court's time, and enormous amounts of BPMC's own time and money in deposing and reviewing documents from literally dozens of witnesses at laboratories which DHS has induced to infringe, when the U.S. Supreme Court is likely to grant certiorari in one or both of the apparently conflicting Eleventh Amendment decisions from separate Circuits recently petitioning for review. To require BPMC to proceed with such litigation expenditures during the interim, while the outcome of the Supreme Court's decision may moot this action or else may convince BPMC not to refile its claims against DHS, would be an enormous waste of both this Court's and the parties' time and resources. Reply at 4-5.

DHS, a state agency, is now the only defendant in the case. Co-defendant Kaiser was dismissed by this court on October 30, 1998 pursuant to a motion filed by BPMC. The only defendant remaining in this action has asserted its argument that it is a state actor and immune under Eleventh Amendment jurisprudence. Though DHS is correct that the Supreme Court has yet to actually grant certiorari in any of these cases, this court notes that the petitions are pending and that the issues directly relate to a controlling issue in this case. If DHS is entitled to immunity under the Eleventh Amendment, it will be unnecessary for this court to inquire into the scope of the '693 Patent. Although not required to do so, BPMC has provided a valid reason for the dismissal.

Though largely discretionary, the court must determine whether the defendant will suffer legal prejudice when deciding a motion to dismiss an action without prejudice. *See Westlands*, 100 F.3d at 96. As stated above, neither uncertainty about the unresolved dispute nor the expense occurred in defending the lawsuit constitute legal prejudice. *See id.* at 97.

DHS argues that BPMC has been dilatory in its effort to litigate and in bringing the present motion. DHS argues that it has produced over 6,000 documents to BPMC, but that BPMC has not produced anything in return. DHS argues that "[t]he record of the last year demonstrates BPMC's repeated resistance to any review of the merits of its Patent." Opposition at 4. In its Reply, BPMC points out that these statements are misleading because BPMC has turned over thousands of documents to Kaiser, DHS' former co-defendant. In a sworn declaration, an attorney for BPMC confirmed that DHS had received copies of the documents provided Kaiser. *See* Dhuey Decl. at ¶¶ 5-6. The case itself was filed in the Southern District of California shortly after BPMC received a favorable ruling dismissing a declaratory judgment action brought by Kaiser. BPMC filed this motion to voluntarily dismiss the action approximately five months after the action was initiated, which is relatively early in the litigation process. Additionally, BPMC brought the current motion within a week after a petition was filed with the Supreme Court appealing the Federal Circuit's decision. The court finds that BPMC has not been delinquent in its efforts to litigate this case or bring this motion.

The court therefore grants BPMC's motion to voluntarily dismiss the case. The purpose of Rule 41(a)(2) is to allow dismissal of the action unless the defendant will be prejudiced. *See Stevedoring*, 889 F.2d at 920. As stated above, this dismissal will not result in any legal prejudice or unfairness. The court does not find DHS' argument that BPMC will now be able to leisurely review the DHS documents persuasive. Not only has BPMC demonstrated that DHS has access to the documents it has turned over to Kaiser, but there is no credible evidence before the court that BPMC will use its time to review thousands of documents in a case that has been dismissed. If the case is refiled, each party will be provided with the opportunity for discovery as is provided for by the Federal Rules. No legal advantage will be gained by dismissing the action at this time. The court finds DHS' request that dismissal of the action be conditioned on BPMC completing all currently pending and overdue discovery unnecessary to preserve DHS' interests and costly, considering the case may not be refiled. Those interests will be preserved by the rules of discovery that will govern any future action.

DHS also argues that any future action should be subject to the same schedule as this case. The court finds that this argument is illogical since it is uncertain when, if ever, a new action would be filed. The court will not impose a series of dates on a party when the entire matter is dismissed.

This court also finds that it is unnecessary to impose the other conditions suggested by DHS. DHS provides no explanation as to why it is necessary for this court to mandate that any future action be filed with this court or to mandate that discovery conducted to this point be utilized. As explained above, it is unnecessary for this court to impose any conditions concerning discovery because no injustice has been shown at this point and the parties would be under discovery rules in any future action. Though DHS points out that they have incurred expenses and spent time preparing for this case, the Ninth Circuit has held that such considerations do not constitute legal prejudice. *See Westlands*, 100 F.3d at 97 ("We have explicitly stated that the expense incurred in defending a lawsuit does not amount to legal prejudice.").

DHS raises concerns about duplicative work. But this concern is inconsistent with its request that the court condition its dismissal upon a simultaneous order that BPMC continue providing discovery in the dismissed action. Presumably, DHS wants to receive the extra documents so that there will be no tactical advantage for BPMC, which has many of the DHS documents. Reviewing documents for a case that was dismissed, however, is not an efficient use of an attorney's time. BPMC is attempting to dismiss this action to save resources. Instead of demonstrating legal prejudice, DHS asks for conditions that ensure that work continues on a dismissed case when it already has access to volumes of documents that BPMC has provided to Kaiser. The Federal Rules will ensure that discovery is conducted fairly and thoroughly in any future litigation. Even if this case is brought again at a future time, the parties can stipulate that they do not need to turn over documents that the other side already has, or a similar ruling can be sought from the magistrate judge. In its Reply, BPMC is amenable to this idea. *See* Reply at 9 ("BPMC does not quarrel with DHS's future use of BPMC's already-produced (to DHS or KAISER) bates-stamped documents and interrogatory responses to DHS in any future litigation between BPMC and DHS."). There is no need for this court to impose restrictions on an action that is being dismissed when the defendant has not demonstrated legal prejudice.

Lastly, DHS argues that BPMC should pay DHS' costs and attorneys fees. As the Ninth Circuit has stated, "[i]mposition of costs and fees as a condition for dismissing without prejudice is not mandatory however." *Westlands*, 100 F.3d at 97. Both parties have conducted this litigation in good faith. The matter has only been pending for approximately five months, and BPMC brought this current motion within a week after the petition for the Federal Circuit decision was filed with the Supreme Court. The issue of Eleventh Amendment immunity is also a new issue in the litigation between BPMC and DHS. The issue was not raised in the litigation dismissed by the federal court in the Northern District of California. Because BPMC has brought this motion for dismissal at an early stage in the litigation, because it apparently has been brought in good faith, and because no inequities will result from granting the dismissal, the court will not award attorneys fees or costs.

IV. Conclusion

For the foregoing reasons, the court **GRANTS** BPMC's Motion to Voluntarily Dismiss the action. This dismissal is without prejudice. This terminates the current action.

IT IS SO ORDERED.

11/17/98	s/Judith N. Keep
Date	Judge Judith N. Keep United States District Court Southern District of California

cc: ALL PARTIES
MAGISTRATE JUDGE JAMES F. STEVEN

APPENDIX D

UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF CALIFORNIA

No. C 97-3211 MMC

KAISER FOUNDATION HEALTH PLAN, INC., a California non-profit public benefit corporation, et al.,
Plaintiffs

v.

BIOMEDICAL PATENT MANAGEMENT CORPORATION, a California corporation,
Defendant

ORDER GRANTING DEFENDANT'S MOTION FOR RECONSIDERATION; DISMISSING ACTION; VACATING HEARING DATE

Maxine M. Chesney, District Judge
Filed May 6, 1998

On March 27, 1998, the Court granted defendant Biomedical Patent Management Corporation ("BPMC") leave to file a motion for reconsideration of the Court's order of March 3, 1998, denying BPMC's motions to dismiss the complaint and the complaint in intervention for improper venue. BPMC filed its motion for reconsideration on April 3, 1998, noticed for hearing on May 8, 1998. Plaintiffs Kaiser Foundation Health Plan ("Kaiser Plan"), Kaiser Foundation Hospitals ("Kaiser Hospitals"), and Kaiser Foundation Health Plan of the Northwest ("Kaiser Plan Northwest") (collectively, "Kaiser plaintiffs"), and plaintiff in intervention the California Department of Health Services ("DHS") timely filed oppositions on April 17, 1998. On April 24, 1998, BPMC timely filed a reply. The Court deems the motion appropriate for determination on the papers submitted by the parties.

Having read and considered the papers filed in support of and in opposition to the motion, the Court finds that venue is not proper in this district.

The Court is persuaded by the additional briefing that for purposes of establishing venue under 28 U.S.C. § 1391(b)(2), the relevant conduct is that of the defendant and not the plaintiff. Accordingly, Kaiser plaintiffs and DHS may not establish venue based on their own activities in the forum.

The Court finds that neither Kaiser plaintiffs nor DHS has made a sufficient showing under 28 U.S.C. § 1391(b)(2) based on the conduct of BPMC, nor has a sufficient showing been made by either Kaiser plaintiffs or DHS to establish venue under 28 U.S.C. §§ 1391(b)(1) and (c).

For the foregoing reasons, BPMC's motion for reconsideration is GRANTED. The action is DISMISSED without prejudice pursuant to Fed.R.Civ.P. 12(b)(3).

The Clerk shall close the file.

IT IS SO ORDERED.

Dated: May 6, 1998 s/Maxine M. Chesney
Maxine M. Chesney
United States District Judge

APPENDIX E

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

No. 98-1434

KAISER FOUNDATION HEALTH PLAN, INC., [*ET AL.*],
Plaintiffs-Appellants,

and

CALIFORNIA DEPARTMENT OF HEALTH SERVICES,
Plaintiff,

v.

BIOMEDICAL PATENT MANAGEMENT CORPORATION,
Defendant-Appellee.

ORDER

November 18, 1998

The parties having so agreed, it is

ORDERED that the proceeding is DISMISSED under Fed. R. App. P. 42(b).

APPENDIX F

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

No. 3:06-cv-0737-MHP

BIOMEDICAL PATENT MANAGEMENT CORP.,
a California Corporation,
Plaintiff

v.

STATE OF CALIFORNIA, DEPARTMENT OF HEALTH
SERVICES, an arm of the State of California,
Defendant

COMPLAINT FOR PATENT INFRINGEMENT

Filed Feb. 2, 2006

DEMAND FOR JURY TRIAL
Related Case Notice (Civil L.R. 3-12): No. C97-3211, Judge Maxine M. Chesney (dismissed Nov. 20, 1998)

Plaintiff Biomedical Patent Management Corporation ("BPMC") hereby alleges as follows:

THE PARTIES

1. Plaintiff is a California corporation, with its principal place of business in San Diego.

2. Defendant is the State of California, Department of Health Services ("Cal. DHS"), with its headquarters in Sacramento.

JURISDICTION

3. This action arises from the United States patent laws, Title 35, United States Code. Subject matter jurisdiction is conferred on the Court by 28 U.S.C. §§ 1331, 1338(a). Venue is proper in this District under the provisions of 28 U.S.C. §§ 1391 and 1400(b).

INTRADISTRICT ASSIGNMENT

4. This is an intellectual property action and is therefore exempt from the Court's Assignment Plan under Civil L.R. 3-2(c).

NOTICE OF RELATED CASE

5. This action is a refiling of the counterclaim to an action previously filed by Defendant in this District: Case No. C97-3211 MMC. That action was dismissed for improper venue on Nov. 20, 1998. Pursuant to Civil L.R. 3-12, Plaintiff shall promptly file an Administrative Motion to Consider Whether Cases Should be Related upon assignment of this action to a District Judge.

FACTUAL ALLEGATIONS

6. On 17 October 1989, U.S. Patent Number 4,874,693 ("the '693 Patent"), entitled "Method for assessing placental dysfunction" was duly and legally issued to Mark Bogart, Ph.D. By assignment, BPMC now owns and holds all rights to enforce the '693 Patent, and is solely entitled to recover for all past, present and future acts of infringement.

7. Cal. DHS performs laboratory services, and induces others to provide services, which infringe and are continuing to so infringe the '693 Patent.

8. On information and belief, BPMC alleges that prior to Cal. DHS's acts of infringement, it was aware of the '693 Patent, and its application to the services performed by Cal. DHS. On information and belief, therefore, Cal. DHS's infringement is willful, making this an exceptional case entitling BPMC to treble damages and attorneys fees.

9. BPMC seeks a reasonable royalty and other forms of monetary damages.

CLAIM ONE – LITERAL PATENT INFRINGEMENT

10. For its first claim, BPMC incorporates herein paragraphs 1 through 9, inclusive.

11. Cal. DHS literally infringed the '693 Patent.

CLAIM TWO – PATENT INFRINGEMENT UNDER THE DOCTRINE OF EQUIVALENTS

12. For its second claim, BPMC incorporates herein paragraphs 1 through 9, inclusive.

13. Cal. DHS has infringed the '693 Patent under the doctrine of equivalents.

CLAIM THREE – LITERAL PATENT INFRINGEMENT BY INDUCEMENT

14. For its third claim, BPMC incorporates herein paragraphs 1 through 9, inclusive.

15. Cal. DHS has induced one or more other persons to literally infringe the '693 Patent.

CLAIM FOUR – PATENT INFRINGEMENT BY INDUCEMENT UNDER THE DOCTRINE OF EQUIVALENTS

16. For its fourth claim, BPMC incorporates herein paragraphs 1 through 9, inclusive.

17. Cal. DHS has induced one or more other persons to infringe the '693 Patent under the doctrine of equivalents.

Wherefore, BPMC prays for judgment and relief on its claims against Cal. DHS including:

i) an award of damages, together with prejudgment interest, to compensate BPMC for Cal. DHS's infringement of BPMC's patent rights;

ii) an award of treble the damages because of the willful nature of Cal. DHS's infringement of BPMC's patent rights;

iii) an award of prejudgment interest on the above damages from the date(s) incurred during the past six years until judgment is entered herein;

iv) an award of costs, expenses and reasonable attorneys fees, and post-judgment interest on all of the above amounts; and

v) such other and further relief as this Court may deem just and proper.

BPMC hereby demands a trial by jury on its claims.

Respectfully submitted on this 2nd day of February, 2006,

By: s/Andrew J. Dhuey
ANDREW J. DHUEY

RICHARD KIRK CANNON
ANDREW J. DHUEY
Attorneys for Plaintiff,
BIOMEDICAL PATENT
MANAGEMENT CORP.

APPENDIX G

UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF CALIFORNIA

No. 98 CV 0897R (LAB)

BIOMEDICAL PATENT MANAGEMENT CORPORATION,

Plaintiff

v.

STATE OF CALIFORNIA, DEPARTMENT OF HEALTH SERVICES,

Defendant

COMPLAINT

Filed May 12, 1998

Local Rule 3.1 Designation:
e. Patent
JURY TRIAL DEMANDED
IMPORTANT NOTICE TO CLERK PER L.R. 40.1:
This action is a re-filing of Case No. 98 CV 0881

Plaintiff, BIOMEDICAL PATENT MANAGEMENT CORPORATION, for its complaint against Defendant, STATE OF CALIFORNIA, DEPARTMENT OF HEALTH SERVICES alleges:

PARTIES

1. Plaintiff is a California corporation with a principle place of business in this judicial district.

2. On information and belief, Plaintiff alleges that Defendant STATE OF CALIFORNIA, DEPARTMENT OF HEALTH SERVICES is an agency of the state of California one of its principal places of business within this judicial district.

JURISDICTION

3. This action is for patent infringement arising under the patent laws of the United States, Title 35, United States Code. Subject matter jurisdiction is conferred on this court by 28 U.C. § 1338(a).

4. This court has personal jurisdiction over Defendant because Defendant's activities within this judicial district are substantial, continuous and systematic. In addition, Plaintiff is informed and believes that the causes of action alleged herein arise out of or are related to Defendant's activities within this judicial district.

VENUE

5. Venue is proper 28 U.S.C. §§ 1391(c) and 1400(b), because Defendant "resides" in this judicial district for purposes of the foregoing venue statutes. In addition, Plaintiff is informed and believes that Defendant has committed acts of patent infringement within this judicial district.

FACTUAL ALLEGATIONS

6. On 17 October 1989, United States Patent 4,874,693 ("the '693 Patent"), entitled "Method for assessing placental dysfunction" was duly and legally issued to Mark Bogart, Ph.D. By assignment, Plaintiff now owns and holds all rights to enforce the

‘693 Patent, and is solely entitled to recover for all past, present and future acts of infringement.

7. Defendant performs laboratory services, and induces others to provide services, which infringe and are continuing to so infringe the ‘693 Patent.

8. On information and belief, Plaintiff alleges that prior to Defendant’s acts of infringement, it was aware of the ‘693 Patent and its application to the services performed by Defendant. On information and belief, therefore, Defendant’s infringement is willful, making this an exceptional case entitling Plaintiff to treble damages and attorneys fees.

9. Defendant’s infringement of Plaintiff's exclusive rights under the ‘693 patent is damaging and will continue to damage Plaintiff's business, causing irreparable harm for which there is no adequate remedy at law. Defendant’s infringement will continue unless enjoined by this Court.

10. Plaintiff has been injured by Defendant’s infringing acts in an amount not yet determinable. Plaintiff seeks a reasonable royalty and other forms of monetary damages.

CLAM ONE – LITERAL PATENT INFRINGEMENT

11. For its first claim, Plaintiff incorporates herein paragraphs 1 through 10, inclusive.

12. Defendant has literally infringed the ‘693 Patent.

CLAIM TWO – PATENT INFRINGEMENT UNDER THE DOCTRINE OF EQUIVALENTS

13. For its second claim, Plaintiff incorporates herein paragraphs 1 through 10, inclusive.

14. Defendant has infringed the '693 Patent under the doctrine of equivalents.

CLAM THREE – LITERAL, PATENT INFRINGEMENT BY INDUCEMENT

15. For its third claim, Plaintiff incorporates herein paragraphs 1 through 10, inclusive.

16. Defendant has induced one or more other persons to literally infringe the '693 Patent.

CLAIM FOUR – PATENT INFRINGEMENT BY INDUCEMENT UNDER THE DOCTRINE OF EQUIVALENTS

17. For its fourth claim, Plaintiff incorporates herein paragraphs 1 through 10, inclusive.

18. Defendant has induced one or more other persons to infringe the '693 Patent under the doctrine of equivalents.

Wherefore, Plaintiff prays for judgment and relief against Defendant including:

(a) a preliminary and permanent injunction against Defendant, its directors, administrators, agents, servants, employees, and attorneys, and those persons in active concert or participation with Defendant, enjoining them from the aforesaid acts of infringement;

(b) an award of damages, together with prejudgment interest, to compensate Plaintiff for Defendant's infringement of Plaintiff's patent rights;

(c) an award of treble the damages because of the willful nature of Defendant's infringement of Plaintiff's patent rights;

(d) an award of prejudgment interest on the above damages from the date(s) incurred during the past six years until judgment therefor is entered herein;

(e) an award of costs, expenses, and reasonable attorneys' fees, and post-judgment interest on all of the above amounts; and

(f) such other and further relief as this Court may deem just and proper.

PLAINTIFF DEMANDS A TRIAL BY JURY ON ALL ISSUES.

Dated: 11 May 1998.

ANDREW J. DHUEY

RICHARD KIRK CANNON
LAW OFFICES OF CANNON
AND ASSOCIATES

s/Andrew J. Dhuey
by Andrew J. Dhuey
Attorneys for Plaintiff
BIOMEDICAL PATENT
MANAGEMENT CORPORATION

APPENDIX H

UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF CALIFORNIA

No. C97-3211 MMC

KAISER FOUNDATION HEALTH PLAN, INC., a California non-profit public benefit corporation; [et al.],

Plaintiffs

v.

BIOMEDICAL PATENT MANAGEMENT CORPORATION, a California Corporation,

Defendant

STATE OF CALIFORNIA, DEPARTMENT OF HEALTH SERVICES,

Plaintiff in Intervention

COMPLAINT IN INTERVENTION FOR DECLARATORY JUDGMENT OF PATENT INVALIDITY AND NON-INFRINGEMENT

Filed Dec. 15, 1997

Plaintiff-In-Intervention STATE OF CALIFORNIA, DEPARTMENT OF HEALTH SERVICES ("DHS"), by its undersigned attorneys, complains of the defendant and avers as follows:

JURISDICTION

1. This Court has jurisdiction over this action pursuant to 28 U.S.C. §§ 2201 and 2202 (declaratory judgments) and § 1338(a) (patents).

VENUE

2. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391(b) and 1400(a) by virtue of the fact that a substantial part of the events giving rise to Plaintiff's claims have occurred in this district.

THE PARTIES

3. Plaintiff-In-Intervention is the Department of Health Services for the State of California.

4. DHS is informed and believes that Plaintiffs KAISER FOUNDATION HEALTH PLAN, INC. and KAISER FOUNDATION HOSPITALS are California non-profit public benefit corporations, with their principal place of business at Oakland, California. KAISER FOUNDATION HEALTH PLAN OF THE NORTHWEST is an Oregon non-profit corporation with its principal place of business at Portland, Oregon.

5. DHS is informed and believes that defendant BIOMEDICAL PATENT MANAGEMENT CORPORATION ("BPMC") is a California corporation, with its principal place of business in San Diego, California.

ACTUAL CONTROVERSY

6. In this action, DHS seeks a declaration that U.S. Patent No. 4,874,693, "Method for Assessing Placental Dysfunction," (the "Patent") is invalid or that DHS does not infringe the Patent. The Patent is purportedly owned by defendant BPMC whose prin-

cipal, Mark Bogart, is the named inventor of the Patent.

7. The Patent relates to screening for birth defects in pregnant women in the second trimester.

8. The State of California has initiated a statewide program in which DHS, in cooperation with Kaiser Foundation Health Plan, Inc. and Kaiser Foundation Hospitals and several other laboratories around the State of California, provides a maternal blood test, known as the "triple marker" test, to screen for birth defects in pregnant women. In conjunction with these labs, DHS offers this test to over 300,000 pregnant women in the State of California each year.

9. A dispute has arisen between BPMC and providers of this test, including DHS and Kaiser, concerning this Patent. BPMC contends that the Patent covers the triple marker test and that entities providing the test are responsible for past damages as well as ongoing royalty obligations. Refusal to license by other labs has resulted in at least two lawsuits filed by BPMC.

10. BPMC has approached DHS alleging that DHS's program infringes the Patent and seeking royalty payments. In discussions between DHS and BPMC representatives, BPMC made clear that it had brought suits for patent infringement against other labs that did not accept its non-negotiable licensing terms. DHS believes that its triple marker test does not infringe the Patent or that the Patent is invalid.

DECLARATORY JUDGMENT

11. DHS has not infringed and is not now infringing the Patent.

12. The Patent is invalid because the alleged invention fails to satisfy the conditions for patentability specified in Title 35, United States Code including §§ 101, 102, 103 and 112.

PRAYER FOR RELIEF

WHEREFORE, DHS prays:

1. that this Court enter an Order declaring that DHS has not infringed the Patent;

2. that this Court enter an Order declaring that the Patent is invalid;

3. that this Court award DHS its attorneys' fees, costs and expenses in this action; and

4. that this Court grant such other and further relief as this Court may deem just.

Respectfully submitted,

s/Robert P. Taylor
Robert P. Taylor
Albert P. Halluin
Edwin H. Wheeler
Buckmaster deWolf
David Smith
HOWREY & SIMON
301 Ravenswood Avenue
Menlo Park, CA 94025-3453

Attorneys for Plaintiff-Intervenor
STATE OF CALIFORNIA,
DEPARTMENT OF HEALTH
SERVICES

Dated: December 15, 1997

APPENDIX I

UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF CALIFORNIA

No. C97-3211 MMC

KAISER FOUNDATION HEALTH PLAN, INC., a California non-profit public benefit corporation; [et al.],

Plaintiffs

v.

BIOMEDICAL PATENT MANAGEMENT CORPORATION, a California Corporation,

Defendant

STATE OF CALIFORNIA, DEPARTMENT OF HEALTH SERVICES,

Plaintiff in Intervention

DEFENDANT'S ANSWER AND COUNTERCLAIM TO COMPLAINT-IN-INTERVENTION

Filed Mar. 16, 1998

TRIAL BY JURY DEMANDED

Defendant Biomedical Patent Management Corporation ("BPMC") hereby answers and counterclaims to the complaint-in-intervention filed by the State of California, Department of Health Services

("DHS"). BPMC submits this answer and counterclaim over its objection to venue in this judicial district. BPMC respectfully disagrees with the Court's denial of its motions to dismiss this action for improper venue, and preserves its objections to venue for appeal.

ANSWER

1. BPMC admits that this Court has subject matter jurisdiction over this action.

2. BPMC denies that venue is proper in this district.

3. BPMC lacks sufficient knowledge to admit or deny DHS' party allegation in paragraph 3 (all references to paragraphs are to paragraphs in DHS' complaint-in-intervention), and, on that basis, denies those allegations.

4. BPMC lacks sufficient knowledge to admit or deny DHS' party allegation in paragraph 4, and, on that basis, denies those allegations.

5. BPMC admits that it is a California corporation with its principal place of business in San Diego, California.

6. BPMC admits that it owns U.S. Patent No. 4,874,693 ("'693 Patent"), that Mark Bogart, Ph.D., is the president of BPMC and that Dr. Bogart is the named inventor of said patent; BPMC denies the remainder of paragraph 6.

7. While not admitting to any limitation on the scope of the '693 Patent, BPMC admits the contents of paragraph 7.

8. BPMC lacks sufficient knowledge to admit or deny DHS' allegations in paragraph 8, and, on that

basis, denies those allegations. BPMC admits that a dispute exists between itself and certain other entities regarding the '693 Patent, including DHS and Plaintiffs in this action.

9. BPMC denies that it contends that the '693 Patent covers the "triple marker test"; BPMC in fact contends that the '693 Patent covers only a portion of the procedures done as part of the "triple marker test". BPMC admits that at least two other laboratories' infringement of the '693 Patent coupled with their refusal to enter into a license agreement has resulted in patent infringement litigation.

10. BPMC lacks sufficient knowledge as to DHS' beliefs to admit or deny the last sentence of paragraph 10. BPMC admits the remainder of paragraph 10.

11. BPMC denies the allegations of paragraph 11.

12. BPMC denies the allegations of paragraph 12.

Wherefore, BPMC prays:

a. that this Court enter judgment in favor of BPMC on DHS's claim for declaratory relief;

b. that this Court award BPMC its attorneys fees in defending DHS's complaint-in-intervention; and

c. that this Court grant such further and other relief as this Court may deem proper.

BPMC hereby demands a trial by jury on DHS' complaint-in intervention.

COUNTERCLAIM

JURISDICTION

13. This counterclaim arises from the United States patent laws, Title 35, United States Code. Subject matter jurisdiction is conferred on the Court by 28 U.S.C. §§ 1331, 1338(a).

PERSONAL JURISDICTION AND VENUE

14. This court has personal jurisdiction over DHS because DHS has filed a complaint-in-intervention in this action, and the instant counterclaim is compulsory within the meaning of Federal Rule of Civil Procedure 13(a).

15. Venue is proper under 28 U.S.C. §§ 1391(c) and 1400(b), because DHS has filed a complaint-in-intervention in this action, and the instant counterclaim is compulsory within the meaning of Federal Rule of Civil Procedure 13(a).

FACTUAL ALLEGATIONS

16. On 17 October 1989, the '693 Patent, entitled "Method for assessing placental dysfunction" was duly and legally issued to Mark Bogart, Ph.D. By assignment, BPMC now owns and holds all rights to enforce the '693 Patent, and is solely entitled to recover for all past, present and future acts of infringement.

17. DHS performs laboratory services, and induces others to provide services, which infringe and are continuing to so infringe the '693 Patent.

18. On information and belief, BPMC alleges that prior to DHS' acts of infringement, it was aware of the '693 Patent and its application to the services performed by DHS. On information and belief, there-

fore, DHS' infringement is willful, making this an exceptional case entitling BPMC to treble damages and attorneys fees.

19. DHS' infringement of BPMC's exclusive rights under the '693 patent is damaging and will continue to damage BPMC's business, causing irreparable harm for which there is no adequate remedy at law. DHS' infringement will continue unless enjoined by this Court.

20. BPMC has been injured by DHS's infringing acts in an amount not yet determinable. BPMC seeks a reasonable royalty and other forms of monetary damages.

CLAIM ONE – LITERAL PATENT INFRINGEMENT

21. For its first claim, BPMC incorporates herein paragraphs 1 through 20, inclusive.

22. DHS has literally infringed the '693 Patent.

CLAIM TWO – PATENT INFRINGEMENT UNDER THE DOCTRINE OF EQUIVALENTS

23. For its second claim, BPMC incorporates herein paragraphs 1 through 20, inclusive.

24. DHS has infringed the '693 Patent under the doctrine of equivalents.

CLAIM THREE – LITERAL PATENT INFRINGEMENT BY INDUCEMENT

25. For its third claim, BPMC incorporates herein paragraphs 1 through 20, inclusive.

26. DHS has induced one or more other persons to literally infringe the '693 Patent.

CLAIM FOUR – PATENT INFRINGEMENT BY INDUCEMENT UNDER THE DOCTRINE OF EQUIVALENTS

27. For its fourth claim, BPMC incorporates herein paragraphs 1 through 20, inclusive.

28. DHS has induced one or more other persons to infringe the '693 Patent under the doctrine of equivalents.

Wherefore, BPMC prays for judgment and relief on its counterclaim against DHS including:

a. a preliminary and permanent injunction against DHS, its directors, administrators, agents, servants, employees, and attorneys, and those persons in active concert or participation with DHS, enjoining them from the aforesaid acts of infringement;

b. an award of damages, together with prejudgment interest, to compensate BPMC for DHS' infringement of BPMC's patent rights;

c. an award of treble the damages because of the willful nature of DHS' infringement of BPMC's patent rights;

d. an award of prejudgment interest on the above damages from the date(s) incurred during the past six years until judgment therefor is entered herein;

e. an award of costs, expenses, and reasonable attorneys' fees, and post-judgment interest on all of the above amounts; and

f. such other and further relief as this Court may deem just and proper.

BPMC hereby demands a trial by jury on its counterclaim.

Dated: 16 February 1998.

Respectfully submitted,

s/Andrew J. Dhuey
ANDREW J. DHUEY
RICHARD KIRK CANNON
Specially Appearing as Attorneys for Defendant
BIOMEDICAL PATENT
MANAGEMENT CORPORATION

APPENDIX J

United States Patent
Bogart

Patent Number: 4,874,693
Date of Patent: Oct. 17, 1989

METHOD FOR ASSESSING PLACENTAL DYSFUNCTION

Inventor:	**Bogart, Mark** (3432 Pershing Ave., San Diego, CA 92104)
Appl. Number:	**917,985**
Filed:	**October 10, 1986**

Int. Cl.^{4} **G01N 33/53**; G01N 33/543; G01N 33/577; C12Q 1/68

U.S. Cl. **435/7**; 435/6; 436/518; 436/544; 436/548; 436/814; 436/818

Field of Search 435/7; 436/548, 500, 436/506, 544, 65, 814, 817, 818, 518

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Gocke et al., *Verh. Dt. Ges. Path.*, 66, 141, (1982).
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Lustig et al., *Am. J. Med. Genetics,* 31, 211, (1988).

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ABSTRACT

A method is presented for detecting placental dysfunction that is diagnostic of aneuploid chromsomal abnormalities. It is particularly useful for diagnosing pregnancies at risk for fetal aneuploid chromosome abnormalities, and consists of quantitating the hormone human chroionic gonadotropin (HCG) alone or in combination with the free alpha subunit of HCG (alpha-HCG). In a preferred embodiment of the invention, bodily fluids from women between 18 and 25 weeks of gestation are assayed using an immunoassay. Levels of 2.5 or more multiples of the median value for normal pregnancies (MOM) for HCG and/or alpha-HCG are indicative of fetal chromosome abnormalities. This test will detect approximately 70% of fetuses with chromosome aneuploidy.

17 Claims, 3 Drawing Sheets [omitted]

METHOD FOR ASSESSING PLACENTAL DYSFUNCTION

BACKGROUND OF INVENTION

A major cause of birth defects is due to chromosome abnormalities, particularly aneuploidy. An increased incidence of aneuploid babies born to women over 35 years of age was first identified by Penrose in 1933 and now forms the basis for genetic counseling in prenatal diagnosis. While the risk for chromosomal disorder in the liveborn offspring of women ages 35 and older ranges from 1.21% at age 35 to 8.12% at age 46, the contribution of these older mothers to the total incidence of chromosomally abnormal babies is only about 25%, due to the vastly larger numbers of babies born to women under 35 years of age. This means that currently by performing amniocentisis on the approximately 6% of pregnant women who are 35 or older, 25% of chromosomally abnormal fetuses can be detected. Conversly, this also means that about 75% of chromosomally abnormal features are born to the younger age group of women who are not offered genetic amniocentisis.

While using maternal age as a screening parameter is clearly useful, other parameters or tests are needed, particularly biochemical tests which can be offered to pregnant women regardless of age. In this regard Merkatz et al have shown that low levels of maternal serum alphafetoprotein (AFP) are somewhat correlative wit fetal chromosome abnormalities. However, this test appears to have limited wide spread applicability since recent studies have shown that in pregnant women with low AFP levels only about 20% actually carried a chromosomally abnormal fetus.

SUMMARY OF INVENTION

An assay is described for detecting placental dysfunction that is indicative of chromosomally abnormal fetuses, having a success rate of up to about 80% and premised on measuring maternal levels of human chorionic gonadotropin hormone (HCG) alone, or HCG and the free alpha subunit of HCG (alpha-HCG). The assay consists of measuring the levels of HCG or HCG and alpha-HCG in the bodily fluids of pregnant women using immunoassay techniques. A wide variety of immunochemical assays can be employed including competitive and noncompetitive binding assays, performed in solution or on solid surfaces. Particularly useful assay reagents are antibodies that recognize epitopes on the beta subunit of the alpha subunit of HCG.

The assay is particularly diagnostic of fetal chromosome abnormalities when performed on females that are between 18 and 25 weeks gestation. The assay has a low false positive rate of about 1% when an elevated level of HCG alone or HCG and alph-HCG is the indicator of fetal abnormality. Levels of HCG and/or alpha-HCG of 2.5 or more multiples of the median values for normal pregnancies (MOM) are indicative of fetal chromosome abnormality. Additional features of the subject invention are that the assay indicates chromosome abnormality independent of the age of the mother. Because this assay evaluates HCG which is primarily produced by the fetal placenta, any abnormality that affects the production or control of production of HCG may be detected. In essence, this assay evaluates placental function and is, therefore, not limited to only detecting chromosomally abnormal fetuses.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 presents a graphic profile of AFP for patients carrying normal and chromosomally abnormal fetuses. (● = trisomy 21; □ = trisomy 13; ▲ = trisomy 18; X = XO and XO/XY mosaics; o = 10 q+)

FIG. 2 shows HCG levels expressed as international units/per milliliter from patients carrying both normal and chromosomally abnormal fetuses. MOM stands for ""multiples of the median". (● = trisomy 21; □ = trisomy 13; ▲ = trisomy 18; X = XO and XO/XY mosaics; o = 10 q+)

FIG. 3 presents alpha-HCG levels present in maternal serum from patients carrying normal and chromosomally abnormal fetuses. MOM stand for multiples of the median. (● = trisomy 21; □ = trisomy 13; ▲ = trisomy 18; X = XO and XO/XY mosaics; o = 10 q+)

DETAILED DESCRIPTION OF INVENTION

The subject invention assay pesents a method for assessing plcental function that is useful for detecting chromosomal abnormalities in fetuses carried by women that are approximately 18 to 25 weeks of gestation. The assay is premised on detecting elevated levels of HCG and/or alpha-HCG. In the preferred embodiment of the invention, these molecules are detected and quantitated using antibodies that recognize specific epitopes present on the beta and on the alpha chains of HCG. The assay is maximally reliable when it is conducted on bodily fluids taken from women that are between 18 and 25 weeks of gestation. This is because in normal pregnancies HCG levels fluctuate dramatically prior to 18 weeks, but remain stable from 18-25 weeks. The subject invention assay relies on detecting abnormal levels (particularly, but not exclusively, elevated levels) of HCG and/or alpha-HCG rather than on just the presence or absence of HCG and/or alpha-HCG. Therefore, values from normal pregnancies need to be accounted for when determining if a women has an abnormal hormone level. Thus, this is most readily done between 18-25 weeks of gestation.

It is well known that different types of immunoassays, and even the same type assay performed in different laboratories, give different results in terms of absolute quantities of a particular hormone measured. The use of multiples of the median value for normal pregnancies (MOM) to determine which patients have abnormal levels is a convenient (but not the only) method to account for the variation in hormone measurements. By using MOM, various assay methods and procedures can be used to produce the same diagnostic result even if the absolute quantities of a hormone measured differ with differing immunoassay techniques. It will be appreciated that the subject assay may also be useful for detecting fetal chromosome abnormalities earlier than 18 weeks of gestation provided techniques such as MOM calculations are used to account for normal hormone levels for each week of gestational age.

While it is anticipated that HCG and alpha HCG will be primarily assayed in serum or urine of pregnant women, there is in fact no reason for limiting the assay to these two types of bodily fluids. It is known that HCG and alpha-HCG are found in tears and other bodily fluids, and that the levels of these molecules increase in these fluids during pregnancy as they do in urine and serum. Consequently, the subject assay can be conducted on virtually any bodily fluid that contains HCG and/or alpha-HCG.

The assay described herein is an immunoassay that utilizes antibodies that bind to epitopes on the beta and alpha subunits of HCG that are used to detect the quantities of HCG and free alpha-HCG. We have found that levels of HCG equal to or greater than 2.5 MOM (17 IU/ml) are detected in 56% of pregnant women with chromosomally abnormal fetuses. Additionally, we have found that elevated levels of the free alpha sub-unit of HCG allow detection of an additional 12% of chromosomally abnormal fetuses. Thus, by measuring both HCG and alpha-HCG approximately 70% of women with chromosomally abnormal fetuses can be detected with a false positive rate of only about 1%. It should also be noted that very low levels of HCG (less than 0.25 MOM) were observed in 8% of women with chromosomally abnormal fetuses. Therefore, using both elevated and low levels of HCG and/or alpha-HCG, up to nearly 80% of chromosomally abnormal fetuses can be detected with a total false positive rate of about 4%. Comparative testing with the only other biochemical indicator of chromosomal defects, alpha fetoprotein (AFP), shows that AFP only detects about 25% of those women that carry a chromosomally abnormal fetuses with a false positive rate of about 6%.

In performing the immunochemical assay for either HCG, or HCG and alpha HCG, bodily fluids containing these molecules and antibodies to either one or both will be employed in forming a detectable "immunocomplex". While the exact physical nature of the complex is not fully known, its formation, nonetheless makes possible the subject assay. Formation of an immunocomplex can be achieved in many ways. For example, it is to be anticipated that a competitive equilibrium assay can be utilized where all the reactants are in solution, or where at least one of the antibodies is attached to a solid surface.

In the solution competitive equilibrium assay situation, where the sample contains the antigens and antibodies to HCG and alpha-HCG, bodily fluids containing these molecules and antibodies to either one or both will be employed in forming a detectable "immunocomplex".

Formation of an immunocomplex can be achieved in many ways. For example it is to be anticipated that a competitive equilibrium assay can be utilized where all the reactants are in solution, or where at least one of the antibodies is attached to a solid surface. In the solution competitive equilibrium assay situation, the sample containing the antigens and antibodies to HCG, alpha-HCG or both of these molecules are brought together in an aqueous medium, normally having a pH of about 6-9.

Tracer amounts of labeled antigens are added to the sample to complete for binding to their respective antibodies with HCG and/or alpha HCG present in the sample. Partitioning on labeled HCG and/or alpha-HCG occurs via being bound and unbound to antibody. Bound labeled amounts of these molecules may then be separated from their unbound counterparts, and the amount of HCG and/or alpha-HCG determined in accordance with the nature of the label, by comparison to control samples similarly treated and containing known amounts of these molecules.

In the above types of assays, all the materials can be brought together simultaneously, or the sample can be combined with the requisite antibodies followed by the addition of labeled HCG, and/or alpha-HCG. Further incubation steps may be involved between the various additions usually not being less than 5 minutes or more than about 24 hours. Additionally, either a rate or equilibrium measurement may be involved.

The second class of immunoassays that are anticipated to be employable in the subject invention are referred to as "2-site" or "sandwich" assays. Here, a fluid sample from a pregnant women is incubated with an excess of antibody bound to at least one solid surface and directed against HCG, and/or alpha-HCG. Subsequently, labeled second antibodies, also in excess but directed against a second determinant on HCG and/or alpha-HCG are incubated with the immunocomplex formed with the first antibody attached to the solid substrate. The presence of the labeled second antibodies on the surface of the immunocomplex can then be determined by suitable means depending on the type of label used. A variety of "sandwich assay" are described in the prior art, and they are hereby incorporated by reference. Particularly useful are assays shown in U.S. Pat. No. 4,376,110 and U.S. Pat. No. 4,244,940.

It will be apparent to those skilled in the art that a two site assay is particularly effective for determining HCG and/or alpha HCG. For example, an antibody (monoclonal or polyclonal) specific to the beta chain of HCG can be attached to the solid surface which in turn will bind intact HCG. Subsequently, a labeled second antibody, again mono or polyclonal, directed against the alpha subunit of HCG can be employed to bind the alpha chain, and thereby indicate the presence of the immunocomplex on the solid substrate. It will be appreciated that the assay is also workable if antibody against the alpha subunit of HCG is affixed to the solid substrate and the labeled second antibody binds to the beta subunit of HCG.

In order to assay free alpha-HCG in a sample containing HCG, antibodies that do not recognize alpha HCG in combination with the beta subunit should be utilized. One such antibody exists and has been described by Pandian et al, *Clin. Chem.* 31, 980 (1985). Other monoclonal antibodies having unique alpha-HCG binding capacity can be generated by the hybridoma techniques well known to those skilled in the art.

Depending on the type of immunoassay utilized in the present invention, various labels to monitor the presence of either HCG and/or alpha-HCG or antibodies directed to either of these molecules may be employed. The choice of label will be dictated in part by the sensitivity of the material being assayed, as well as cost and availability of reagents.

A variety of labels are well known and routinely used in immunoassays such as radionuclides (particularly I125), enzymes, fluorescers, magnetic particles, stable free radicals, etc. Prior art illustrative of these labels are U.S. Pat. Nos. 3,654,090; 3,867,517; 3,996,345 and 4,020,151.

There are routinely used in immunoassays a variety of fluorescers including fluorescein, densyl, rhodamines, acradines, etc. Suitable enzymes employable in this invention include beta-galactosidase, alkaline phosphatase and horseradish peroxidase, as well as others well known to those skilled in the art.

As allued to above, a variety of radionuclides are employable as suitable levels. Moreover, the procedures for attaching or metabolically labeling proteins with these labels are well known. For instance, radiolabeling proteins with iodine can be achieved by the lactoperoxidase method well known to those skilled in the art, or may involve indirect binding using the Bolton-Hunter or similar reagent.

Assaying for either HCG and/or alpha-HCG can be effected using antibodies that are polyclonal or monoclonal. The former are generated using HCG, the beta subunit of HCG or alpha-HCG, and injecting these molecules into an animal to effect an immune response, thereby resulting in the reproduction of antibodies. Suitable animals are sheep, goats, mice, rats and rabbits, though other animals may also be used. Polyclonal antibody can be prepared from crude sera by absorption or salt precipitation techniques to yield highly specific antibodies. These techniques are well known to those skilled in the art. It should be noted that both polyclonal and monoclonal antibodies to HCG are commercially available.

In addition to preparing polyclonal antibodies, it is well known that monoclonal antibodies can be generated that are useful in a variety of immunochemical assays, particularly "two-site" assays. The procedure for generating monoclonal antibodies is described by Kohler and Milstein, *Nature,* 356, 495-597 (1975). Kohler and Milstein primarily show the preparation of monoclonal antibodies of mouse origin. In addition, monoclonal antibodies of human origin can be prepared as described by Glassy et al in *Monoclonal Antibodies in Cancer,* (Boss et al, eds.; Academic Press: (1983)) and Glassy et al, *National Academy of Sciences, U.S.A.,* 80, 6237 (1983). The method of Heitzmann and Cohn described in *Molecular Biology and Medicine,* 1, 235, 243 (1983) may also be utilized to generate monoclonal antibodies against HCG or alpha-HCG.

If a two site solid phase immunoassay is employed in the subject assay invention, attachment of antibody to the solid substrate may be by procedures known to those skilled in the art, such as absorption or by covalent binding directly or through chemical linkers of sorts also well known to those skilled in the art. Simple methods for carrying out these procedures are given, for example, by Iman and Hornby in *Biochemical Journal,* 129, 255-259 (1972) and Campbell, Hornby & Morris in *Biochemical Biophysical Acta,* 397, 384-392 (1985). Also it should be noted that solid surfaces chemically pretreated and suitable for binding antibody can be purchased commercially.

A preferred embodiment of the subject invention will involve secondary antibodies carrying a label wherein the label is capable of effecting a color change indicative of the presence of HCG and/or alpha-HCG. Generally this will involve a label comprising an enzyme molecule that hydrolyzes a colorless substrate to produce a detectable color change of the solution bathing the solid surface, or a change in the color of the solid surface. In either instance, the degree of color can be monitored to indicate the levels of HCG and/or alpha-HCG.

Particularly useful two site assays are those in which two solid surfaces are used to assay HCG and/or alpha-HCG. By attaching the appropriate antibodies to two separate sites on one or more surfaces simultaneous assay of both HCG and alpha-HCG may be accomplished using a single aliquot of fluid.

A wide variety of enzymes are suitable for attachment to antibody. For example, horseradish peroxidase can be employed, as well as beta-galactosidase, glucose oxidase, alkaline phosphatase, etc. These enzymes utilize primarily tetrazolium salts well known to those skilled in the art as substrate. The procedures for generating horseradish peroxidase antibody conjugates and purifying the same are described by Arendo in *Methods of Enzymology,* 73, 166-173 (1981).

The following examples are for illustrative purposes and are not intended to be a delineation of all ways by which HCG and/or alpha-HCG can be assayed.

EXAMPLE 1

Alpha-fetoprotein (AFP) and HCG Levels in Maternal Serum

HCG levels were measured in women carrying chromosomally normal and abnormal fetuses. A total of 74 women carrying normal fetuses and 25 women carrying chromosomally abnormal fetuses were studied. Table 1 below shows the type of chromosomal abnormalities of the 25 abnormal fetuses. Table 2 below presents the AFP levels measured and the gestational age when the samples were obtained from the various mothers carrying chromosomally abnormal fetuses. Also shown in Table 2 are the levels of HCG and alpha-HCG. These data are presented in graphic form in FIGS. 1, 2 and 3.

[TABLE 1 AND TABLE 2 OMITTED]

The data were gathered using the method of Ruoslahti et al, described in *Natl. Canc. Inst.,* 49, 623-650 (1972) for measuring AFP using a radioimmunoassay. Modifications in the published procedure include separating bound AFP from free AFP using goat anti-rabbit gamma globulin as the second antibody. Highly purified AFP was used as the standard and was calibrated against the Center for Disease

Control AFP standard. The intra-assay varition was 9.4% and the interassay variation was 11.2%.

The assay employed to detect and quantitate HCG was that of Pandian et al., *Endocrinology,* 107, 1564-1571 (1980), also described above. This is a radiommunoassay and utilizes an antibody that recognizes HCG by binding to an epitope on the beta chain of the molecule. The antibody exhibits little or no cross activity with alpha-HCG, lutenizing hormone, follicle stimulating hormone, or thyrotropin. HCG standard was calibrated against the World Health Organization, Second International Reference preparation. The intra-assay variation was 6.2% and the inter-assay variation was 7.8%. Samples were routinely assayed over a range of dilutions including 1:10, 1:100, 1:1000.

Because maternal serum AFP levels rise with increasing age, it is necessary to obtain a median value for each gestational age for women carrying normal fetuses, to be able to compare this value to AFP levels associated with chromosomally abnormal fetuses. However, because HCG levels do not fluctuate over the gestation period tested (18-25 weeks), HCG levels determined in pregnant women were compared to a single median value derived from maternal serum of women carrying normal fetuses.

FIG. 1 shows the relationship of AFP levels and fetal chromosomal normality or abnormality. FIG. 1 also shows that there were 5 chromosomally abnormal fetuses with AfP levels of 0.5 MOM or less, and one with an AFP level higher than 2.5 MOM. Thus, out of 25 fetuses that were confirmed as being chromosomally abnormal, only 6 (24%) displayed abnormal levels of AFP.

FIG. 2 shows the relationship of maternal serum HCG levels with fetal chromosomal normality or abnormality. The median HCG value for the 74 women carrying normal fetuses during the gestation period of 18-25 weeks was 8.0 International Units/per milliliter. The most interesting feature of FIG. 2 is that it shows 14 serum samples from women carrying chromosomally abnormal features having HCG levels greater than 2.5 MOM, while only 1 serum sample from a women carrying a chromosomally normal fetus had a value greater than 2.5 MOM.

It should also be noted that 2 of 25 samples from women with chromosomally abnormal fetuses had HCG levels less than 0.25 MOM, as did 2 of 74 samples from women with chromosomally normal fetuses.

From a comparative standpoint, it is easily seen that abnormal levels of HCG, particularly elevated levels, are more predictive of having a chromosomally abnormal fetus than are low serum AFP levels.

EXAMPLE 2

Measurement of Alpha-HCG and Relationship to Chromosomally Abnormalities

The materials and methods described in this Example are similar to those described in Example 1 with the exception that alpha-HCG was assayed. A radioimmunoassay procedure was utilized, as described above by Pandian et al, (1985). A serum sample from each of the cases shown in Table 2 was incubated with a monoclonal antibody (A 109) that recognizes alpha-HCG. I125 labeled alpha-HCG was utilized to compete with alpha-HCG present in the sample. The assay is specific for alpha-HCG and exhibits no cross reactivity with the beta subunit of

HCG, luteinizing hormone, follicle stimulating hormones, or thyrotropin hormone. However, because it does exhibit a slight crossreactivity (2.4% on a molar basis) with HCG, additional accuracy is realized by correcting for this cross reactivity. It was determined that the assay has an intra-assay variation of 5.1% and an inter-assay variation of about 6.0%.

Using the Pandian et al (1985) procedure described above, it was shown that alpha-HCG levels are increased in maternal serum from some females carrying chromosomally abnormal fetuses. FIG. 3 presents the results obtained for 74 women carrying normal fetuses that were 18-24 weeks pregnant, and for 25 women that carried chromosomally abnormal fetuses. It can be seen that the median normal alpha-HCG level is about 160 ng/ml. Further, it is apparent that none of the women carrying normal fetuses had an alpha-HCG level equal to or greater than 2.5 MOM. In contrast, 28% of females carrying abnormal fetuses had an alpha-HCG level equal to or greater than 2.5 MOM. It is important to note that of the 7 patients that displayed elevated alpha-HCG levels, 4 of these also exhibited elevated HCG levels. These are cases 989, 8908, 7497 and 9388 shown in Table 2. Three females that presented elevated alpha-HCG had normal levels of HCG. These are cases 8954, 9127 and 8365 shown in Table 2.

EXAMPLE 3

Simultaneous Detection of HCG and Alpha-HCG

The materials and methods described in this example are similar to those in the proceeding examples with the following exceptions. A monoclonal antibody can be attached to a solid surface that recognizes an epitope on alpha-HCG which is available for antibody binding only when alpha-HCG is physically separated from the beta chain of HCG. In addition, a second monoclonal antibody specific to an epitope on the beta chainn of HCG is bound to a separate region on the solid surface. Subsequently, these solid surfaces are immersed in assay sample fluid containing either unknown or known amounts of HCG and alpha-HCG. The assay is run on a sample containing known amounts of HCG and alpha-HCG to obtain data from which to construct a standard curve.

After a period of incubation to permit saturation binding of HCG and alpha-HCG to their respective antibodies, the solid surfaces are washed with a suitable physiological buffer to remove any unbound reactants, and then labeled second antibody is added. The latter can be a monoclonal antibody that recognizes a common epitope on the alpha chain that is bound to the beta chain, and the alpha chain which is not bound to the beta chain. In this instance, the monoclonal antibody can have associated with it an enzyme label capable of yielding a color reaction in the presence of a suitable substrate. Thus, second antibody can be labeled with alkaline phosphatase, beta-galactosidase, or like enzyme.

After an incubation period sufficent to realize discernable color, the reaction can be stopped with either acid or base, and the amount of color present correlated with amounts indicative of HCG and alpha-HCG concentration. The amount of color present can be quantitated using known special photometric techniques.

It will be understood that although the foregoing invention has been described by way of illustration and example, that this is for clarity of understanding, and that there exists a variety of imaginable changes and modifications that may be practiced within the appended claims.

We claim:

1. A method for identifying a pregnant women with substantial risk of gestating a fetus having an aneuploid chromosomal abnormality, comprising

a. combining bodily fluids taken from said female gestating said fetus during the 18th through 25th weeks of her pregnancy in an aqueous buffered assay medium with labeled human chorionic gonadotropin (HCG) hormone, wherein said label provides a detectable signal and antibodies to HCG;

b. determining the amount of labeled HCG either bound or unbound to said antibodies as a measure of HCG in said sample; and

c. comparing the level of said HCG in said sample with levels of HCG measured during the same time interval of pregnancy in women gestating normal fetuses, said comparison being determinative of the presence of the aneuploid abnormality in said fetus.

2. A method according to claim 1 wherein said label is radioactive.

3. A method according to claim 1 wherein said label is an enzyme.

4. A method for identifying a pregnant women with substantial risk of gestating a fetus having an aneuploid chromosomal abnormality, comprising

a. combining bodily fluids taken from said female gestating said fetus during the 18th through 25th weeks of her pregnancy in an aqueous buffered assay medium with labeled human chorionic gonadotropin

(HCG) hormone and labeled alpha-human chorionic gonadotropin (alpha-HCG) hormone, wherei said label provides a detectable signal and antibodies to HCG and alpha-HCG;

b. determining the amount of labeled HCG and labeled alpha-HCG either bound or unbound to said antibodies as a measure of HCG and alpha-HCG in said sample; and

c. comparing the level of said HCG and alpha-HCG in said sample with levels of HCG and alpha-HCG measured during the same time interval of pregnancy in women gestating normal fetuses, said comparison being determinative of the presence of the aneuploid abnormality in said fetus.

5. A method according to claim 4 wherein said label is radioactive.

6. A method according to claim 5 wherein said label is an enzyme.

7. A method for diagnosing placental dysfunction indicative of fetal aneuploid chromosomal abnormalities comprising quantifying elevated levels of human chorionic gonadotropin hormone or its subunits in a bodily fluid taken from the women gestating said fetus during the 18th through 25th weeks of her pregnancy, by:

a. contacting one or more first antibody molecules correspondingly reactive with said gonadotropin hormone or its subunits and which antibodies are attached to one or more solid surfaces with the body fluid to form primary complexes on the solid surfaces, and isolating said primary complexes;

b. contacting said primary complexes with one or more labeled second antibody molecules correspondingly reactive with said gonadotropin hormone or its subunits to form secondary complexes on said one or more solid surfaces, and isolating said second complexes; and

c. comparing the amount of labeled second antibody molecules correspondingly reactive with said gonadotropin hormone or its subunits with amounts of labeled antibody measured for control samples prepared in accordance with steps a and b and taken from women gestating normal fetuses during the same time interval of their pregnancies, said comparison being correlated with the level of gonadotropin hormone or its subunits in said female and determinative of the presence of the aneuploid abnormality in said fetus.

8. A method as described in claim 7 wherein said gonadotropins and/or its subunits are selected from the group consisting of HCG, alpha-HCG, and beta-HCG.

9. A method as described in claim 8 wherein said labeled second antibody molecules comprise enzymes capable of producing a color signal indicative of said gonadotropins and/or its subunits when combined with substrate.

10. A method as described in claim 8 wherein said one or more second antibody molecules correspondingly reactive with said gonadotropins and/or its subunits comprises antibodies selected from the group consisting of polyclonal and monoclonal antibodies.

11. A method for identifying a pregnant women with substantial risk of gestating a fetus having an aneuploid chromosomal abnormality, comprising: a. combining bodily fluids taken from said female ges-

tating said fetus during the 18th through 25th weeks of her pregnancy in an aqueous buffered assay medium with labeled alpha-human chorionic gonadotropin (alpha-HCG) hormone, wherein said label provides a detectable signal and antibodies to alpha-HCG; b. determining the amount of labeled alpha-HCG either bound or unbound to said antibodies as a measure of alpha-HCG in said sample; and c. comparing the level of said alpha-HCG in said sample with levels of alpha-HCG measured during the same time interval of pregnancy in women gestating normal fetuses, said comparison being determinative of the presence of the aneuploid abnormality in said fetus.

12. A method according to claim 11 wherein said label is an enzyme.

13. A method according to claim 12 wherein said label is radioactive.

14. A method as described in claim 1 wherein said chromosomal abnormality is selected from the group consisting of trisomy 21, trisomy 18, trisomy 13, monosomy X, mosaic XO/XY and 46 XY, 10 q+.

15. A method as described in claim 4 wherein said chromosomal abnormality is selected from the groups consisting of trisomy 21, trisomy 18, trisomy 13, monosomy X, mosaic XO/XY and 46 XY, 10 q+.

16. A method as described in claim 7 wherein said chromosomal abnormality is selected from the groups consisting of trisomy 21, trisomy 18, trisomy 13, monosomy X, mosaic XO/XY and 46 XY, 10 q+.

17. A method as described in claim 11 wherein said chromosomal abnormality is selected from the groups consisting of trisomy 21, trisomy 18, trisomy 13, monosomy X, mosaic XO/XY and 46 XY, 10 q+.

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO.: 4,874,693
DATED: October 17, 1989
INVENTOR(S): Mark Bogart

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 1, line 23 "features" should be --fetuses--;
Column 1, line 31 "alphafetoprotein" should be --alpha-fetoprotein--;
Column 1, line 31 "wit" should be --with--;
Column 1, line 53 "alph-HCG" should be --alpha-HCG--;
Column 2, line 23 "pesents" should be --presents--;
Column 2, line 24 "plcental" should be --placental--;
Column 3, line 27 "fetuses" should be --fetus--;
Column 3, line 56 "complete" should be --compete--;
Column 3, line 58 "on" should be --of--;
Column 4, line 9 "women" should be --woman--;
Column 4, line 25 "alpha HCG." should be --alpha-HCG.--;
Column 4, line 59 "densyl" should be --dansyl--;
Column 4, line 64 "allued" should be --alluded--;
Column 4, line 65 "levels" should be --labels--;
Column 5, line 9 "reproduction" should be --production--;
Column 7, line 63 "features" should be --fetuses--;
Column 9, line 4 "chainn" should be --chain--;
Column 10, claim 4, line 1 "wherei" should be --wherein--;
Column 10, claim 7, line 29 "surfaces, and" should be --surfaces thereon, and--.

APPENDIX K

LIST OF CASES IN WHICH STATES HAVE INVOKED FEDERAL PATENT JURISDICTION*

Alabama

Board of Trustees of the University of Alabama v. *Idenix Pharmaceuticals*, 2:2007cv00101 (N.D. Ala. filed Jan. 12, 2007)

Board of Trustees of the University of Alabama v. *Nektar Therapeutics*, No. 5:05-cv-01514 (N.D. Ala. filed July 13, 2005)

Board of Trustees of the University of Alabama v. *University of Houston*, No. 4:2000cv00528 (S.D. Tex. filed Feb. 18, 2000)

California

Regents of the University of California v. *University of Iowa Research Foundation*, 455 F.3d 1371 (Fed. Cir. 2007)

Regents of the University of California v. *DakoCytomation California, Inc.*, No. 2006-1334 (Fed. Cir. filed Apr. 11, 2006)

Lizardtech, Inc. and Regents of the University of California v. *Earth Resource Mapping, Inc.*, 424 F.3d 1336 (Fed. Cir. 2005)

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* These cases were located through searches of the PACER database and represent only those cases that have been filed since the PACER system was implemented by the district courts.

Juvenon, Inc. and Regents of the University of California v. *Vitacost.com, Inc.*, No. 3:04-cv-04804-SI (N.D. Cal. filed Nov. 12, 2004)

Regents of the University of California v. *Actagro, LLC*, 102 Fed. App'x 681 (Fed. Cir. 2004)

Eolas Technologies Inc. and Regents of the University of California v. *Microsoft Corp.*, 2004 U.S. Dist. LEXIS 522 (N.D. Ill. 2004)

Regents of the University of California v. *Monsanto Co.*, No. 3:04-cv-00634-PJH (N.D. Cal. filed Feb. 17, 2004)

Regents of the University of California v. *Micro Therapeutics Inc.*, No. 5:03-cv-05669-JW (N.D. Cal. filed Dec. 16 2003)

State of California Dep't of Transportation v. *Tycor Walls, Inc.*, 2003 U.S Dist. LEXIS 25667 (E.D. Cal. June 3, 2003)

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